UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2003, or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from to
Commission file number 000-21615

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 ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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 ☐ No ☒

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.

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 introducted 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	Determine test kit performance against all expected levels of reactivities in the evaluation of	Test kit manufacturers, clinical laboratories that evaluated test kits, and regulators.

	presence or absence of a particular disease marker.	new, modified and improved test methods.	
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 the support of AIDS Vaccine development program by the National Institute of Allergy and Infectious Diseases (NIAID) branch of the National Institutes of Health (NIH). 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 also, BBI Biotech was re-awarded a 5-year contract from the Food and Drug Administration 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. In 2004, the Company also completed its Phase I studies under a 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) was awarded for the development of a system which would significantly extend the viability and maintain the quality of frozen cells.

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 (including five one-year extension options) with the National Heart, Lung and Blood Institute of the NIH. In 1999, it received a seven-year, $9.6 million repository contract with the National Institute of Allergy and Infectious Disease. In 2000, BBI Biotech was awarded a 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. Subsequent funding has continued. In 2001, BBI Biotech was awarded a $10.3 million NCI five year repository contract. In 2002 BBI Biotech was awarded another subcontract, also valued at $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). In 2002 BBI Biotech also signed a 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. BBI Biotech also signed a contract with Boston University to supply DNA inventory, storage, extraction and genotyping services and was awarded a 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. 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, 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 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.

ITEM 2. PROPERTIES.

The Company owns its corporate offices and diagnostic products manufacturing facility for its BBI Diagnostics operating segment, which is located in a two-story, 32,000 square foot building in West Bridgewater, Massachusetts. The Company has deferred renovation and expansion of this facility during recent years, but believes that any renovations to its facility in West Bridgewater, MA would be sufficient to meet its needs for several years. This building is subject to a $2,500,000 ten year mortgage dated March 31, 2000. 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. Monthly payments on this mortgage are based on a 20 year amortization schedule with a balloon payment representing the remaining balance due in full on March 10, 2010.

The 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. The Company also leases laboratory facilities in Gaithersburg and Frederick, Maryland. The BBI Biotech segment's Gaithersburg facility

contains 36,500 square feet of custom built laboratory and office space, and is occupied under a ten-year lease that expires on October 31, 2007. The Frederick facility contains 35,560 square feet of repository space under a seven-year lease that expires on November 30, 2006. See also Note 13 of Notes to Consolidated Financial Statements hereunder, included in Part II, Item 8 of this Form 10K.

BBI Clinical Laboratories ("BBICL"), a discontinued operation, operated from a 15,000 square foot facility in New Britain CT pursuant to a lease which expires in July 2005. In connection with the sale of substantially all of the assets of BBICL in 2001, the buyer reimbursed the Company for essentially all rental-related costs of this facility during the period February 21, 2001 through December 31, 2001. See also Note 13 of Notes to Consolidated Financial Statements hereunder, included in Part II, Item 8 of this Form 10K.

ITEM 3. LEGAL PROCEEDINGS.

The Company is not a party to any material pending legal proceedings.

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

The Company held a Special Meeting in Lieu of Annual Meeting of Stockholders on October 2, 2003 (the "Meeting"). A total of 6,071,106 shares, or 88.99%, of the Company's Common Stock issued, outstanding and entitled to vote as of the record date, were represented in person or by proxy, at the Meeting. At the Meeting, one proposal was acted upon. The result of the proposal was as follows:

1. Dr. Calvin A. Saravis and Mr. R. Wayne Fritzsche were elected as Class I Directors of the Company, to serve as such until the 2006 Annual Meeting of Stockholders and until their successors have been duly elected and qualified, with 4,895,357 shares voting in favor and 1,175,749 votes withheld for Dr. Saravis, and 4,896,907 shares voting in favor and 1,174,199 votes withheld for Mr. Fritzsche.

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 the fourth quarter of 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 6. SELECTED FINANCIAL DATA

The statement of operations data for each of the fiscal years in the five-year period ended December 31, 2003, and the balance sheet data as of December 31, 2003, 2002, 2001, 2000, and 1999, have been derived from the consolidated financial statements of the Company. This data should be read in conjunction with Item 8-Consolidated Financial Statements and Supplementary Data, and Item 7-Management's Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere herein.

	Year Ended December 31,				
Consolidated Statement of Operations Data: in thousands, except per share data	**2003**	**2002**	**2001**	**2000**	**1999**
REVENUE:					
Products	$ 13,608	$ 12,697	$ 13,093	$ 12,387	$ 14,057
Services	9,688	10,068	8,733	7,083	5,741
Total revenue	23,296	22,765	21,826	19,470	19,798
COSTS AND EXPENSES:					
Cost of products	7,263	6,536	6,338	7,270	7,267
Cost of services	7,602	7,727	6,783	5,581	4,568
Research and development	1,816	2,611	2,303	2,444	3,132
Selling and marketing	3,283	3,286	2,916	2,660	2,831
General and administrative	4,346	4,109	3,977	4,919	3,451
Impairment of intangible asset (1)	—	—	—	1,464	—
Total operating costs and expenses	24,310	24,269	22,317	24,338	21,249
Loss from continuing operations	(1,014)	(1,504)	(491)	(4,868)	(1,451)
Interest (expense) income, net (2)	(272)	(206)	(380)	(1,594)	(413)
Loss from continuing operations before income taxes	(1,286)	(1,710)	(871)	(6,462)	(1,864)
(Provision for) benefit from income taxes (3)	(3)	(3)	(16)	(1,152)	744
Loss from continuing operations before cumulative effect of change in accounting principle	(1,289)	(1,713)	(887)	(7,614)	(1,120)
Cumulative effect of change in accounting principle (2)	—	—	—	(190)	—
Loss from continuing operations	(1,289)	(1,713)	(887)	(7,804)	(1,120)
Income (loss) from discontinued operations	—	225	4,334	(197)	306
Net income (loss)	$ (1,289)	$ (1,488)	$ 3,447	$ (8,001)	$ (814)
Loss per share from continuing operations, basic and diluted	$ (0.19)	$ (0.26)	$ (0.14)	$ (1.43)	$ (0.24)
Net (loss) income per share, basic and diluted	(0.19)	(0.22)	0.56	(1.46)	(0.17)
Number of shares used to calculate net (loss) income per share Basic and Diluted	6,811	6,661	6,204	5,465	4,670

	December 31,				
Consolidated Balance Sheet Data:	**2003**	**2002**	**2001**	**2000**	**1999**
Working capital	$ 7,659	$ 9,197	$ 9,407	$ 3,596	$ 8,615
Net assets from discontinued operations	—	—	—	1,238	1,978
Total assets	16,842	19,843	21,414	22,549	24,934
Long term debt, less current maturities	2,271	2,338	2,403	5,287	7,146
Total stockholders' equity	10,415	12,627	13,440	7,750	13,646
Dividends	—	—	—	—	—

(1) Consists of a $1,464 write-down of goodwill associated with the acquisition of BBI Source Scientific.

(2) Includes $840 of interest expense in 2000 associated with the beneficial conversion feature of the Company's 3% Senior Subordinated Convertible Debentures; $190 of this amount is recorded as a cumulative effect of change in accounting principle in 2000.

(3) Includes $1,135 in 2000 for establishment of a full valuation allowance on the Company's deferred tax assets.

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

Overview

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
Operating 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"). 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 lower levels of contract research activities and a lower level 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 combined with an increased level of billable hours associated with government contract reimbursable work at the 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 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 strong activity in two service contracts related to HIV vaccine development and Hepatitis C work at the Biotech segment (the former resulting from increased revenue for the Biotech segment as the result of increased activity from a subcontractor), and increased grant revenue 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 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, increased collections of accounts receivable and reduced its 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 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. The Company is 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, which could result in dilution to the Company's stockholders. 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	-0-
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.

** 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.

***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.

**** 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 .

*****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 FAIL TO COMPLY WITH GOOD MANUFACTURING PRACTICES IN CONNECTION WITH THE MANUFACTURE OF OUR MEDICAL DEVICE PRODUCTS, WE MAY NOT BE ABLE TO DISTRIBUTE OUR PRODUCTS AND MAY NOT GENERATE PRODUCT REVENUES.

We are also subject to strict FDA good manufacturing practice regulations which govern testing, control and documentation practices, and other post-marketing restrictions on the manufacture of our medical device products. Our IN VITRO diagnostic products and our laboratory instrumentation products are considered "medical device products," as defined by the FDA. Regulatory authorities monitor our ongoing compliance with good manufacturing practices and other applicable regulatory requirements through periodic inspections. If we fail to comply with good manufacturing practices or other regulatory requirements, we may not be able to obtain future pre-market clearances or approvals, or the FDA or other regulatory agencies may impose corrective action requirements, including total or partial suspension of product distribution, injunctions, civil penalties, recall or seizure of products, and criminal prosecution. Any of these events would lead to increased costs and a drain on resources and could reduce our revenues and operating results.

BECAUSE WE CONDUCT OUR BUSINESS WORLDWIDE, CHANGES IN INTERNATIONAL REGULATORY REQUIREMENTS MAY MATERIALLY REDUCE OUR TOTAL REVENUES.

Our international sales accounted for approximately 20% of our total revenues for the year ended December 31, 2003. Our Accurun® External Run Controls products are subject to CE Marking requirements in the European Union.

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. Changes in international regulatory requirements and policies, including both changes in existing restrictions and future restrictions on importation of blood and blood derivatives, could result in reduced international sales, which may materially reduce our total revenues and income.

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.

IF WE CANNOT PROTECT OUR INTELLECTUAL PROPERTY, WE MAY BE UNABLE TO COMPETE EFFECTIVELY.

Our ability to compete effectively with other companies depends in part on our ability to maintain the proprietary nature of our technologies and products. We rely primarily on a combination of trade secrets and non-disclosure and confidentiality agreements to establish and protect our proprietary rights in our technology and products. For the pressure cycling technology developed by our BBI BioSeq subsidiary, we have eleven U.S. and four foreign patents issued as of December 31, 2003. If we have not adequately protected our technology, or if our competitors misappropriate our intellectual property, we could lose market share and our future revenues and operating income could be significantly less than projected.

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. We cannot guarantee that 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.

IF WE ARE UNABLE TO ATTRACT AND RETAIN A NEW CHIEF EXECUTIVE OFFICER, THEN WE MAY NOT BE SUCCESSFUL IN FULLY EXECUTING OUR BUSINESS PLAN.

On February 14, 2003, we announced the termination of our Chairman and Chief Executive Officer; he remains a Director of the Company. A special committee of our Board of Directors was appointed to oversee management of the affairs of the Company until such time as a new Chief Executive Officer is employed. There are a limited number of qualified candidates for the position with the necessary technical background and management experience. We are competing for those candidates with companies that are larger and have greater financial resources than we. If we are not able to attract and retain a new, suitably qualified, Chief Executive Officer within a reasonable period of time, we may not be able to properly evaluate our strategic choices, our existing management may not be able to focus their attention on all necessary management matters and we may not be successful in fully executing our business plan.

IF WE ARE UNABLE TO ATTRACT AND RETAIN HIGHLY QUALIFIED SCIENTIFIC AND MANAGEMENT PERSONNEL, THEN WE MAY NOT BE ABLE TO DEVELOP AND REFINE OUR PRODUCTS AND SERVICES.

Our products and services are highly technical and our key personnel must have specialized training or advanced degrees in order to develop and refine these products and services. There are a limited number of qualified scientific and management personnel who possess

the technical background necessary to adequately understand and improve our products and services. We compete for these personnel with other companies, academic institutions, government entities and other organizations engaged in research and development of products similar to ours. If we are unable to attract and retain scientific and management personnel with the appropriate credentials who are capable of developing and refining our products and services, then our products and services could become inaccurate or unreliable, or could fail to obtain FDA approval and we may be unable to deliver new products.

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 ^{TM} 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company is subject to interest rate risk in connection with its long-term debt. The aggregate hypothetical loss in earnings for one year of those financial instruments held by the Company at December 31, 2003, that are subject to interest rate risk resulting from a hypothetical increase in interest rates of 10 percent is less than $100,000, after-tax. The hypothetical loss was determined by calculating the aggregate impact of a 10 percent increase in the interest rate of each variable rate financial instrument held by the Company at December 31, 2003, that is subject to interest rate risk. Fixed rate financial instruments were not evaluated, as the Company believes the risk exposure is not material.

The Company is exposed to concentrations of credit risk in cash and cash equivalents and trade receivables. Cash and cash equivalents are placed with major financial institutions with high quality credit ratings. Trade receivables credit risk exposure is significant as the Company derives a significant portion of its revenues from a small number of customers. However, this risk is mitigated by the dispersion across different industries and geographies in which the customers operate; in addition to this, approximately 25% of 2003 consolidated revenue was from all branches of the National Institutes of Health, a U.S. Government agency. The Company is exposed to credit-related risks associated with its trade accounts receivable from foreign customers but they are denominated in U.S. dollars mitigating the currency risk.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 967,185	$ 975,649
Marketable securities	4,071	—
Accounts receivable, less allowances of $124,283 in 2003 and $117,671 in 2002	3,495,839	3,701,105
Inventories	6,525,018	7,094,053
Prepaid expenses and other current assets	200,695	303,396
Restricted cash (Note 12)	—	1,000,000
Total current assets	11,192,808	13,074,203
Property and equipment, net	4,725,523	5,826,817
OTHER ASSETS:		
Goodwill and other intangible assets, net	749,907	798,542
Other long-term assets	174,208	143,807
Total other assets	924,115	942,349
TOTAL ASSETS	$ 16,842,446	$ 19,843,369
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,633,263	$ 1,970,517
Accrued employee compensation	1,010,512	898,449
Other accrued expenses	541,857	506,823
Liabilities from discontinued operations (Note 2)	192,801	302,436
Current maturities of long term debt	58,180	79,875
Deferred revenue and other current liabilities	97,508	118,609
Total current liabilities	3,534,121	3,876,709
LONG-TERM LIABILITIES:		
Long term debt, less current maturities	2,271,299	2,337,874

Liabilities from discontinued operations (Note 2)	215,040	408,005
Other liabilities	406,777	593,735
Total Liabilities	6,427,237	7,216,323
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Common stock, $.01 par value; 20,000,000 shares authorized; 6,827,592 and 6,786,335 issued and outstanding at December 31, 2003 and 2002, respectively	68,276	67,863
Additional paid-in capital	21,888,234	21,811,262
Loan receivable from Director and former CEO (Note 12)	(1,000,000)	—
Accumulated deficit	(10,541,301)	(9,252,079)
Total stockholders' equity	10,415,209	12,627,046
TOTAL LIABILITIES & STOCKHOLDERS' EQUITY	$ 16,842,446	$ 19,843,369

The accompanying notes are an integral part of these consolidated financial statements

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2003	2002	2001
REVENUE:			
Products	$ 13,607,808	$ 12,696,830	$ 13,092,771
Services	9,687,882	10,067,807	8,733,336
Total revenue	23,295,690	22,764,637	21,826,107
COSTS AND EXPENSES:			
Cost of products	7,262,815	6,535,429	6,337,437
Cost of services	7,602,321	7,727,137	6,783,329
Research and development	1,816,273	2,611,060	2,303,350
Selling and marketing	3,282,538	3,286,183	2,916,013
General and administrative	4,345,643	4,108,734	3,976,568
Total operating costs and expenses	24,309,590	24,268,543	22,316,697
Operating loss from continuing operations	(1,013,900)	(1,503,906)	(490,590)
Interest income	19,391	41,809	57,515
Interest expense, including beneficial conversion feature (Note 7)	(291,283)	(247,971)	(438,008)
Loss from continuing operations before income taxes	(1,285,792)	(1,710,068)	(871,083)
Provision for income taxes	(3,430)	(2,936)	(15,678)
Loss from continuing operations	(1,289,222)	(1,713,004)	(886,761)
Discontinued operations (Note 2)			
Income from discontinued operations of Clinical Laboratory segment (less income taxes of $0, $0, and $969,000 in 2003, 2002 and 2001, respectively)	—	225,000	4,334,498
Net (loss) income	$ (1,289,222)	$ (1,488,004)	$ 3,447,737
Loss from continuing operations per share, basic & diluted	$ (0.19)	$ (0.26)	$ (0.14)
Income per share from discontinued operations, basic & diluted	$ —	$ 0.03	$ 0.70
Net (loss) income per share, basic & diluted	$ (0.19)	$ (0.22)	$ 0.56
Number of shares used to calculate net (loss) income per share, basic and diluted	6,810,660	6,660,662	6,204,384

The accompanying notes are an integral part of these consolidated financial statements

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

FOR THE YEARS ENDED DECEMBER 31, 2003, 2002 AND 2001

Common Stock		Additional Paid-In Capital	Prepaid Common Stock Subscription	Loan to former CEO & Director	Accumulated Deficit	Total Stockholders' Equity
Shares	$.01 Par Value					

BALANCE, December 31, 2000	5,652,516	$ 56,525	$ 18,904,862	$	$	$ (11,211,812)	$ 7,749,575
Common stock issued in connection with Employee Stock Purchase Plan	15,292	153	26,210	—	—	—	26,363
Conversion of 3% Senior Subordinated Convertible Debentures	801,325	8,013	970,876	—	—	—	978,889
Beneficial conversion feature in connection with 3% Senior Subordinated Convertible Debentures	—	—	(527,519)	—	—	—	(527,519)
Stock based compensation	—	—	30,000	—	—	—	30,000
Stock options and other warrants exercised	163,585	1,636	397,063	—	—	—	398,699
Cancelled Exercise of Paradigm warrants	(500,000)	(5,000)	5,000	—	—	—	—
Tax benefit of stock options exercised	—	—	364,000	—	—	—	364,000
Loan to Officer / Director	—	—	—	—	(525,000)	—	(525,000)
Prepaid Common Stock Subscription, net	—	—	—	1,497,568	—	—	1,497,568
Net Income	—	—	—	—	—	3,447,737	3,447,737
BALANCE, December 31, 2001	6,132,718	$ 61,327	$ 20,170,492	$ 1,497,568	$ (525,000)	$ (7,764,075)	$ 13,440,312
Common stock issued in connection with Employee Stock Purchase Plan	9,749	98	25,343	—	—	—	25,441
Issuance of Common Stock, net	600,000	6,000	1,491,568	(1,497,568)	—	—	—
Stock options and other warrants exercised	43,868	438	123,859	—	—	—	124,297
Repayment of Loan to Officer / Director	—	—	—	—	525,000	—	525,000
Net Loss	—	—	—	—	—	(1,488,004)	(1,488,004)
BALANCE, December 31, 2002	6,786,335	$ 67,863	$ 21,811,262	$ —	$ —	$ (9,252,079)	$ 12,627,046
Common stock issued in connection with Employee Stock Purchase Plan	12,102	121	24,176	—	—	—	24,297
Issuance of Common Stock	29,155	292	(292)	—	—	—	—
Tax benefit of stock options exercised	—	—	53,088	—	—	—	53,088
Loan receivable from Director/former CEO	—	—	—	—	(1,000,000)	—	(1,000,000)
Net Loss	—	—	—	—	—	(1,289,222)	(1,289,222)
BALANCE, December 31, 2003	6,827,592	$ 68,276	$ 21,888,234	$ —	$ (1,000,000)	$ (10,541,301)	$ 10,415,209

The accompanying notes are an integral part of these consolidated financial statements

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2003	2002	2001
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net (loss) income	(1,289,222)	$ (1,488,004)	$ 3,447,737
Less income from discontinued operations	—	225,000	4,334,498
Loss from continuing operations	(1,289,222)	(1,713,004)	(886,761)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	1,246,672	1,302,106	1,415,253
Non-cash interest expense on convertible debentures	—	—	(508,906)
Stock-based compensation	—	—	30,000
Provision for doubtful accounts	8,000	—	55,808
(Gain) on disposal of property and equipment	(548)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	197,266	380,354	(247,378)
Inventories	569,035	(330,908)	(297,596)
Marketable Securities	(4,071)	—	—
Prepaid expenses and other current assets	102,701	(127,121)	60,456
Receivable for income taxes	—	—	212,762
Tax benefit of stock option exercises	53,088	—	—
Other long-term assets	(30,402)	3,119	(19,294)
Accounts payable	(337,254)	303,746	434,074
Accrued employee compensation	112,064	(8,977)	70,622

Other accrued expenses	35,035	(100,181)	(367,602)
Deferred revenue	(21,101)	66,211	22,237
Deferred rent and other liabilities	(186,959)	24,828	(29,262)
Net cash provided by (used in) operating activities	454,304	(199,827)	(55,587)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Payments for additions to property and equipment	(110,195)	(624,581)	(416,202)
Proceeds from sale of property and equipment	14,000	85,651	35,509
Net cash used in investing activities	(96,195)	(538,930)	(380,693)
CASH FLOWS FROM FINANCING ACTIVITIES:			
(Repayments) of convertible debentures	—	—	(1,663,352)
Proceeds from issuance of common stock	24,297	149,738	425,062
Proceeds from prepaid common stock subscription, net of issuance costs	—	—	1,497,568
Loan to officer/director	—	525,000	(525,000)
Pledge of restricted cash as security for loan from bank to Director and former CEO	1,000,000	(1,000,000)	—
Conversion of Pledge of Restricted Cash as Security for Loan from Bank to Director to a Loan Receivable from Director and former CEO (Note 12)	(1,000,000)		
Repayments on line of credit		—	(5,762,635)
Repayments of long-term debt	(88,270)	(67,140)	(82,127)
Net cash used in financing activities	(63,973)	(392,402)	(6,110,484)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:	294,136	(1,131,159)	(6,546,764)
Change in cash and cash equivalents provided by (used in) discontinued operations	(302,600)	(751,108)	7,622,580
Cash and cash equivalents, beginning of year	975,649	2,857,916	1,782,100
Cash and cash equivalents, end of year	$ 967,185	$ 975,649	$ 2,857,916
SUPPLEMENTAL INFORMATION:			
Income taxes paid	$ 3,430	$ 1,112	$ 29,801
Interest paid	251,396	244,407	370,149
NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Capital lease obligations incurred	$ —	$ —	$ 21,242
Conversion of Debentures to equity	—	—	978,889
Issuance of 29,155 and 600,000 shares associated with prepaid stock subscriptions	—	1,497,568	—

The accompanying notes are an integral part of these consolidated financial statements

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Business and Significant Accounting Policies

Boston Biomedica, Inc. ("BBI") and Subsidiaries (together, the "Company") provide infectious disease diagnostic products, laboratory instrumentation, contract research and specialty infectious disease testing services to the *in-vitro* diagnostic industry, government agencies, blood banks, hospitals and other health care providers worldwide as of December 31, 2003. The Company also invests in new technologies related to infectious diseases. The Company is subject to risks common to companies in the biotechnology, medical device and diagnostic industries, including but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with governmental regulations.

As of December 31, 2003, the Company had approximately $7,659,000 in working capital, and had cash and cash equivalents of $967,185 as of December 31, 2003, compared to cash and cash equivalents of $975,649, excluding restricted cash of $1,000,000 at December 31, 2002. In January 2003, the $1,000,000 of restricted cash pledged to a financial institution to secure the Company's limited guaranty of a loan from the financial institution to an entity controlled by Richard T. Schumacher, the Company's former Chairman and Chief Executive Officer, was used to satisfy the Company's guaranty obligation to the financial institution as discussed further below. The Company has experienced operating losses from continuing operations of $1,014,000 and $1,504,000 for the years ended December 31, 2003 and 2002 respectively, while the Company experienced negative cash flows from operations of $200,000 for the year ended December 31, 2002, the Company experienced positive cash flow from operations totaling $454,000 for the year ended December 31, 2003. It is anticipated there may be 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. It plans to manage its future liquidity needs through cost reductions and additional selling initiatives; see also Note 13 of Notes to Consolidated Financial Statements hereunder for additional information relative to a line of credit agreement entered into by the Company in February 2004.

Based on current forecasts and the February 2004 establishment of a line of credit as discussed further in Note 13 of Notes to Consolidated Financial Statements hereunder, 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 resumes incurring negative cash flows, 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 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. The Company is 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. 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 date.

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

(i) Principles of Consolidation

The consolidated financial statements include the accounts of BBI (which includes BBI Diagnostics) and its wholly-owned subsidiaries, BBI Biotech Research Laboratories, Inc. ("BBI Biotech"), BBI Source Scientific, Inc. ("BBI Source"), and BBI BioSeq, Inc. ("BBI BioSeq"). BBI consists primarily of the Diagnostic Products segment as well as the executive corporate office. Effective January 2000, all of the Company's technology related to its drug discovery and vaccine programs, consisting primarily of patents and related sponsored research agreements, was transferred to Panacos Pharmaceuticals, Inc. ("Panacos"), a former wholly-owned subsidiary that the Company formed in October 1999. In November 2000 and in February 2002, Panacos sold equity to third party investors, reducing the Company's ownership to approximately 16%, which is held in non-voting preferred stock. As a result, the Company no longer consolidates the results of Panacos. As of November 14, 2000, the Company's investment in

Panacos was zero and the Company is no longer required to fund Panacos's operations. Therefore, no further losses of Panacos will be recorded by the Company

In February 2001, the Company sold the business and certain assets and liabilities of BBI Clinical Laboratories, Inc. ("BBICL") to a third party in conjunction with its decision to exit the clinical laboratory business segment. In accordance with the provisions of APB No. 30, concerning the reporting of the effects of disposal of a segment of a business, the Company classified the results of BBICL as discontinued operations in the accompanying consolidated statements of operations.

(ii) Use of Estimates

To prepare the financial statements in conformity with generally accepted accounting principles, management is required to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In addition, significant estimates were made in determining the gain on the 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 loans made to employees including sufficiency of collateral, deferred tax assets, the net realizable value of its inventory, as well as an estimate for remaining liabilities associated with discontinued operations.

On an on-going basis, we evaluate our estimates. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from the estimates and assumptions used by management.

(iii) Revenue Recognition

We recognize revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 103, *Update of Codification of Staff Accounting Bulletins* ("SAB 103"). 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;
- We do not retain any specific performance obligations such that the earnings process is not complete;
- The ordered goods are segregated from our inventory and not subject to being used to fill other orders; and
- The goods must be 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 our 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 ensure 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 in accordance with EITF Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables." 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.

(iv) Cash and cash equivalents

The Company's policy is to invest available cash in short-term, investment grade, interest-bearing obligations, including money market funds, municipal notes, and bank and corporate debt instruments. Securities purchased with initial maturities of three months or less are valued at cost plus accrued interest, which approximates fair market value, and are classified as cash equivalents. At December 31, 2003, the Company had cash and cash equivalents of $967,185.

(v) Research and Development Costs

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

(vi) Inventories

Inventory is valued at the lower of cost or market. Certain factors may impact the realizable value of our inventory including, but not limited to, technological changes, market demand, changes in product mix strategy, new product introductions and significant changes to our 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. We treat lower of cost or market adjustments and inventory reserves as an adjustment to the cost basis of the underlying inventory. Accordingly, favorable changes in market conditions are not recorded to inventory in subsequent periods.

(vii) Property and Equipment

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

(viii) Goodwill and Intangible Assets

The Company has classified as intangible assets, costs associated with the fair value of certain assets of the businesses acquired. Intangible assets such as patents, licenses, and intellectual property rights, are being amortized on a straight-line basis over four to sixteen years. Goodwill was amortized through December 31, 2001, using the straight-line method over periods ranging up to fifteen years; accumulated amortization was $510,500 as of December 31, 2001. In June 2001, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets". The Company adopted SFAS No. 142 effective January 1, 2002. Under SFAS No. 142, amortization of goodwill ceased and the Company assesses the realizability of these assets annually and whenever events or changes in circumstances indicate it may be impaired. Such events or circumstances generally include the occurrence of operating losses or a significant decline in earnings associated with one or more of the Company's reporting units. The Company estimates the fair value of its reporting units by using forecasts of discounted cash flows. When impairment is indicated, any excess of carrying value over fair value is recorded as a loss. An impairment analysis of remaining goodwill performed as of December 31, 2003 pursuant to the requirements of that accounting pronouncement concluded no impairment had occurred; see Note 5.

(ix) Long-Lived Assets and Deferred Costs

In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through the undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and records the impairment as a reduction in the carrying value of the related asset and a charge to operating results. While the Company's current and historical operating losses and cash flow are indicators of impairment, the Company completed an annual test for impairment at December 31, 2003 and determined that such long-lived assets was not impaired.

Deferred costs include primarily external legal costs associated with the Company's efforts in obtaining long term financings, such as a mortgage and a line of credit. These costs are amortized to expense on a straight line basis over the life of the related financing agreements.

(x) Income Taxes

The Company utilizes the assets and liability method of accounting for income taxes. Under this method, deferred taxes arise from temporary differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance is provided for net deferred tax assets if, based on the weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Tax credits are recognized when realized using the flow through method of accounting. In the year ended December 31, 2000, the Company established a full valuation allowance for all of its deferred tax assets based on applicable accounting standards and in consideration of incurring three consecutive years of losses (see Note 9).

(xi) Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, are principally cash and cash equivalents, and accounts receivable. The Company places its cash and cash equivalents with high credit quality financial institutions. The Company's total cash and cash equivalents at December 31, 2003, are deposited in financial institutions in which deposits are insured under the Federal Deposit Insurance Corporation (up to the level required by law of $100,000 per depositor); in addition, one financial institution provides additional insurance for all funds on deposit via the Depositors Insurance Fund, the latter being a private, industry-sponsored deposit insurance company. The Company limits credit risk in cash equivalents by investing only in short-term, money market accounts. Concentration of credit risk with respect to accounts receivable is limited to certain customers to whom the Company makes substantial sales (see Note 6). The Company does not require collateral from its customers. To reduce risk, the Company routinely assesses the financial strength of its customers and, as a consequence, believes that its trade accounts receivable credit risk exposure is limited.

(*xii) Deferred Revenue*

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

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

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

Potentially dilutive securities having a net effect of 6,692, 164,002 and 9,531 common shares were not included in the computation of diluted loss per share because to do so would have been antidilutive for the years ended December 31, 2003, 2002 and 2001, respectively. For the years ended December 31, 2003, 2002 and 2001, options outstanding having exercise prices greater than the average fair market price of common shares totaled 902,125, 181,000, and 1,087,287, respectively.

(xiv) Segment Reporting

SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information," establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires selected information about operating segments in interim financial reports. It also establishes standards for related disclosures about products and services, geographic areas and major customers. Disclosures required by this new standard are included in Note 6 of Notes to Consolidated Financial Statements hereunder.

(*xv*) ***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 adoption of this pronouncement in year 2003 did not have a material impact on the accompanying consolidated financial statements.

(***xvi) Stock-Based Compensation***

Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS 123), requires that companies either recognize compensation expense for grants of stock options and other equity instruments based on fair value or provide pro forma disclosure of net income (loss) and net income (loss) per share in the notes to the financial statements. At December 31, 2003, the Company has six stock-based compensation plans, which are described more fully in Note 12. The Company accounts for those plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. Accordingly, no compensation cost has been recognized under SFAS 123 for the Company's employee stock option plans. Had compensation cost for awards under those plans been determined based on the grant date fair values, consistent with the method required under SFAS 123, the Company's net income (loss) and net income (loss) per share would have been reduced to the pro forma amounts indicated below:

	2003	2002	2001
Net (loss) income - as reported	$ (1,289,222)	$ (1,488,004)	$ 3,447,737
Add back: Stock-based compensation in net (loss) income, as reported	—	—	—
Deduct: Stock-based employee compensation expense determined under fair value based methods for all awards, net of related tax effects	(496,040)	(1,017,123)	63,754
Net (Loss) Income - pro forma	$ (1,785,262)	$ (2,505,127)	$ 3,511,491
Basic and Diluted net income (loss) per share - as reported	$ (0.19)	$ (0.22)	$ 0.56
Basic and Diluted net income (loss) per share - pro forma	$ (0.26)	$ (0.38)	$ 0.57

The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations in accounting for its employee stock options. Under APB 25, because the exercise price of employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recorded. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS 123).

Pro forma information regarding net income and earnings per share is required by SFAS 123 and has been determined as if the Company had accounted for its employee stock options under the fair value method of that statement. The fair value of these options was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions for 2003, 2002 and 2001.

	2003	2002	2001
Risk-free interest rate	2.96%	2.74%	4.12%
Volatility factor	78.42%	90.88%	99.17%
Weighted average expected life	5.72	4.2	4.0 years
Expected dividend yield	—	—	—

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

(2) Disposition of Assets

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

The Company'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. The major component of this accrual is the estimated lease exit and facility related costs ($308,000), with the remainder for other miscellaneous costs associated with exiting this business segment; see also Note 13 of Notes to Consolidated Financial Statements hereunder. The Company recorded an after-tax gain of $4,334,000 in 2001, and an additional $225,000 gain in 2002; the gain may be subject to future adjustments as the Company completes the process of exiting this business and permanently closing the facility. The remaining closing costs include an estimate to dispose of any remaining assets and retire all existing liabilities including the facility lease as of December 31, 2003. The Company utilized in 2001 certain prior period net operating loss carryforwards, previously reserved for by the Company, to partially offset the income tax effect of this gain. All financial data presented in the accompanying consolidated financial statements has been reclassified to reflect discontinued operations of this segment of the business for all periods presented. Revenues from discontinued operations, net of intercompany eliminations of $0, were $973,000 in the period January 1, 2001 to February 20, 2001 (date of sale).

A summary of the change in total short term and long term net liabilities from discontinued operations is as follows:

Total short term and long term net liabilities from discontinued operations, 12/31/02:	$	710,441
State income taxes, net		(7,051)
Third party audits		(81,344)
Facility Lease and associated costs		(196,123)
Other expenses, net		(18,082)
Total short term and long term net liabilities from discontinued operations, 12/31/03:	$	407,841

(3) Inventories

The Company purchases human plasma and serum from various private and commercial blood banks. Upon receipt, such purchases generally undergo comprehensive testing, and associated costs are included in the value of raw materials. Most plasma is manufactured into Basematrix and other diagnostic components to customer specifications. Plasma and serum with the desired antibodies or antigens are sold or manufactured into Quality Control Panels, Accurun® External Run Controls, and reagents ("Finished Goods"). Panels and reagents are unique to specific donors and/or collection periods, and require substantial time to characterize and manufacture due to stringent technical specifications. Panels play an important role in diagnostic test kit development, licensure and quality control. Panels are manufactured in quantities sufficient to meet expected user demand, which may exceed one year. Inventory also includes component parts used in the manufacture of laboratory instrumentation and commencing in 2002, PCT products. Inventory balances at December 31, 2003 and 2002 consisted of the following:

	2003	2002
Raw materials	$ 3,549,826	$ 3,170,988
Work-in-process	1,124,883	1,988,585
Finished goods	1,850,309	1,934,480
	$ 6,525,018	$ 7,094,053

(4) Property and Equipment

Property and equipment at December 31, 2003 and 2002 consisted of the following:

	2003	2002
Laboratory and manufacturing equipment	$ 3,415,224	$ 3,399,055
Management information systems	3,587,432	3,594,295
Office equipment	937,336	929,328
Automobiles	145,520	166,761
PCT demonstration equipment	210,536	157,573
Leasehold improvements	2,896,731	2,881,090
Land, building and improvements (1)	2,690,913	2,687,661
	13,883,692	13,815,763
Less accumulated depreciation and amortization	9,158,169	7,988,946
Net book value	$ 4,725,523	$ 5,826,817

(1) includes the Company's West Bridgewater, MA facility, which serves as collateral to an existing mortgage; see Note 7 "Debt".

Depreciation and amortization expense for the years ended December 31, 2003, 2002 and 2001 was approximately $1,197,000, $1,246,000 and $1,327,000, respectively.

At December 31, 2003, BBI Source, BBI Biotech and BBI Diagnostics had approximately $374,000, $1,338,000 and $2,560,000 in fully depreciated assets still in use, respectively.

In accordance with Statement of Position ("SOP") 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use", the Company capitalized approximately $448,000 of internal labor and related costs, in 1999, in connection with its ERP System Implementation. These costs are included in the Management Information Systems line item and are being depreciated over the same life as the system, 5 years. Annual depreciation expense related to these capitalized costs was approximately $90,000 for each of the three years ended December 31, 2003, 2002 and 2001.

(5) Goodwill and Other Intangible Assets

Other intangible assets consist of specifically identified intangible assets. Goodwill is the excess of any purchase price over the estimated fair market value of net tangible assets acquired not allocated to specific intangible assets. Goodwill and other intangible assets at December 31, 2003 and 2002 consisted of the following:

	2003	2002
Patents, Licenses and Other Intangibles	$ 778,156	$ 884,902
Less accumulated amortization	(255,333)	(313,444)
subtotal - other intangible assets excluding goodwill	522,823	571,458
Goodwill	737,584	737,584
Less accumulated amortization	(510,500)	(510,500)
subtotal - net goodwill	227,084	227,084
Total net goodwill and other intangible assets	$ 749,907	$ 798,542

Included in intangible assets as of December 31, 2003 is $227,084 of goodwill associated with BBI Source Scientific, Inc. Amortization expense of other intangible assets for the years ended December 31, 2003, 2002, and 2001 was approximately $49,000, $56,000 and $79,000, respectively. The net book value of the remaining other intangible assets excluding goodwill, as of December 31, 2003 is comprised of approximately $523,000 of acquired PCT patents which is being amortized to expense on a straight line basis at the rate of $48,635 per year over the remaining useful life. The estimated annual future amortization expense of other intangible assets excluding goodwill is as follows:

2004	$ 48,635
2005	$ 48,635
2006	$ 48,635
2007	$ 48,635
2008	$ 48,635
2009 and thereafter	$ 279,648

On July 9, 2003, the Company announced that Mr. Schumacher, the Company's former Chairman and Chief Executive Officer, 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. 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 Agreement, Mr. Schumacher will continue in an advisory role directing the Company's Pressure Cycling Technology (PCT) and BBI Source Scientific activities. PCT is the Company's novel and patent protected technology that uses cycles of hydrostatic pressure to control biomolecular interactions; BBI Source Scientific,

Inc. is the Company's laboratory instrumentation subsidiary, which developed and manufactures the PCT Barocycler™ instrument. Using the assumptions associated with revised business plans, the Company has estimated future net undiscounted cash inflows and cash outflows. In 2002, the Company adopted SFAS 142; the Company performed an initial test for impairment upon the adoption of SFAS No. 142 at June 30, 2002, and determined that goodwill was not impaired. The Company completed an annual test for impairment at December 31, 2003 and December 31, 2002 and has determined that goodwill has not been impaired.

The following pro forma adjusted net income has been prepared as if SFAS. No. 142 had been applied retroactively:

	Year Ended December 31, 2001
Net income	$ 3,447,737
Add back: Goodwill amortization	21,627
Adjusted net income	$ 3,469,364
Amounts per common share, basic and diluted:	
Adjusted net income	$ 0.56

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

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

The Company had four operating segments as of December 31, 2003 and 2002 as a result of its decision in late 2000 to exit the clinical laboratory segment of the business. The Diagnostics segment serves the worldwide in vitro diagnostics industry, including users and regulators of their test kits, with quality control products, and test kit components. The Biotech segment pursues third party contracts to help fund the development of products and services for the other segments, primarily with agencies of the United States Government. The Laboratory Instrumentation segment (BBI Source Scientific, Inc.) sells diagnostic instruments primarily to the worldwide in vitro diagnostic industry on an OEM basis, and also performs in-house instrument servicing. The PCT segment consists of research and development primarily in pressure cycling technology ("PCT"). The Company performs research in the development of PCT, with particular focus in the areas of nucleic acid purification and pathogen inactivation. The Company announced the availability for commercial sale of its PCT products in late September of 2002. PCT Revenue to date consists primarily of both private and public (NIH) funding of segment research and, commencing in late 2002, from the sale of PCT products. Most of the expenditures incurred by this segment are for research and development expenses, and general management expenses including patent costs.

The Company's underlying accounting records are maintained on a legal entity basis for government and public reporting requirements, as well as for segment performance and internal management reporting. Inter-segment sales are recorded on a "third party best price" basis and are significant in measuring segment operating results. The following segment information has been prepared in accordance with the internal accounting policies of the Company, as described above. Prior year data has been restated, where feasible, to conform to the current year presentation format.

Operating segment revenues for the years ended December 31, 2003, 2002 and 2001 were as follows:

	2003	2002	2001
Diagnostics	$ 12,097	$ 11,611	$ 11,489
Biotech	9,667	10,162	9,181
Laboratory Instrumentation	1,799	2,374	2,365
PCT	674	717	392
Eliminations	(941)	(2,099)	(1,601)
Total revenue	$ 23,296	$ 22,765	$ 21,826

Operating segment income (loss) for the years ended December 31, 2003, 2002 and 2001 were as follows:

	2003	2002	2001
Diagnostics	$ 1,704	$ 1,478	$ 1,674
Biotech	(274)	(319)	(212)
Laboratory Instrumentation	(892)	(507)	(460)
PCT	(1,552)	(2,156)	(1,493)
Total loss from operations	$ (1,014)	$ (1,504)	$ (491)

Operating segment depreciation and amortization expense for the years ended December 31, 2003, 2002 and 2001 were as follows:

	2003	2002	2001
Diagnostics	$ 500	$ 538	$ 598

Biotech	538	573	593
Laboratory Instrumentation	71	107	140
PCT	138	84	84
Total depreciation and amortization	$ 1,247	$ 1,302	$ 1,415

Identifiable operating segment assets are all located in the United States, and as of December 31, 2003 and 2002 were as follows:

	2003	2002
Corporate	$ 1,277	$ 2,141
Diagnostics	9,447	10,281
Biotech	3,903	4,844
Laboratory Instrumentation	1,234	1,826
PCT	981	751
Total assets	$ 16,842	$ 19,843

Operating segment capital expenditures for the years ended December 31, 2003, 2002 and 2001 were as follows:

	2003	2002	2001
Diagnostics	$ 35	$ 139	$ 205
Biotech	45	322	207
Laboratory Instrumentation	—	5	4
PCT	30	158	21
Total capital expenditures	$ 110	$ 624	$ 437

Revenues by geographic area for the years ended December 31, 2003, 2002 and 2001 were as follows:

	2003	2002	2001
United States	$ 18,624	$ 19,460	$ 18,389
Europe	2,680	2,209	2,397
Pacific Rim	1,225	620	624
Total all others	767	476	416
Total	$ 23,296	$ 22,765	$ 21,826

Revenues of Product and Service classes in excess of 10% of consolidated revenues from continuing operations (excluding inter-segment sales) for the years ended December 31, 2003, 2002 and 2001 were as follows:

	2003	2002	2001
Quality Control Products	$ 10,055	$ 7,909	$ 8,343
Government Contracts	8,667	7,370	7,617
Diagnostic Components	1,898	3,182	2,629
Laboratory Instrument Products	1,524	1,654	1,895

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 NIH accounted for approximately 25%, 31% and 31%, respectively, of total consolidated revenues from continuing operations of the Company.

(7) Debt

Effective June 30, 1999, the Company entered into an amended revolving line of credit agreement (the "Amended Line") with its bank, increasing the facility to $10 million from $7.5 million. The interest rate of the Amended Line at the Company's option was based on either the base rate plus ¼% or LIBOR plus 2.75%; carries a facility fee of ¼% per annum, payable quarterly; and was collateralized by substantially all of the assets of the Company, excluding real property. Borrowings under the Amended Line were limited to commercially standard percentages of accounts receivable, inventory and equipment. The Amended Line contains covenants regarding the Company's total liabilities to tangible net worth ratio, minimum debt service coverage ratio, and maximum net loss. The Amended Line further provided for restrictions on the payment of dividends, incurring additional debt, and the amount of capital expenditures. In February 2001, the Company utilized a portion of the proceeds from the sale of BBICL to pay off in full the outstanding balance (together with accrued interest) on this line of credit, at which time the bank released all liens associated with this line of credit and terminated the line of credit. There were no payment defaults at any time associated with this line of credit. See also Note 13 hereunder.

On August 25, 2000, the Company entered into Securities Purchase Agreements providing for the issuance of $3,250,000 (face value) 3% Senior Subordinated Convertible Debentures due August 25, 2003 (the "Debentures"). Proceeds to the Company, net of a 5% original issue discount and debt issuance costs, amounted to $2,858,000, of which $327,000 has been allocated to the relative fair value of the associated common stock purchase warrants. The fair value of the warrants was determined using the Black Scholes option-pricing model and the following assumptions: a risk free interest rate of 6.02%, a volatility factor of 91.17%, a contractual life of 5 years and no expected dividend yield. The Company then allocated the proceeds of the Debentures, net of the original issue discount ($3,087,500), on a pro-rata basis using the calculated fair value of the warrants ($318,000) and the fair value of the Debentures ($2,685,000). This resulted in proceeds of approximately $327,000 and $2,761,000 being allocated to the relative fair value of the warrants and the

Debentures, respectively. The Debentures are convertible into the Company's common stock commencing November 24, 2000, at a conversion price equal to the lesser of (i) $3.36 per share or (ii) 90% of the average of the five lowest volume weighted average sales prices of Common Stock as reported by Bloomberg L.P. during the twenty-five business days immediately preceding the date on which the Debenture holders notify the Company of their intention to convert all or part of the Debenture into Common Stock. In connection with this transaction, the Company issued warrants, expiring August 2005, to purchase up to 135,556 shares of the Company's common stock at an exercise price of $3.60 per share. Interest on the Debentures was payable quarterly in arrears commencing September 30, 2000. The Debentures are subordinate to both the Company's line of credit (which was terminated in February 2001) and mortgage on its West Bridgewater, MA facility. The Company may elect at any time to redeem all or any portion of the remaining unpaid principal amount of the Debentures for cash. In addition, upon receipt of a notice of conversion from a holder of the Debentures, the Company may elect to redeem that portion being converted for cash in lieu of common stock of the Company. In both cases, the redemption price equals the number of shares of common stock into which the Debenture being redeemed is convertible, times the average closing bid price of the Company's common stock for the five preceding trading days.

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

Original issue discount and associated debt issuance costs of $162,500 and $230,000, respectively, are being amortized ratably over the three-year life of the underlying debt as additional interest expense. Also, in accordance with Emerging Issues Task Force Issues 98-5 and 00-27, proceeds of $840,000 have been allocated to the beneficial conversion feature of the Debentures by decreasing the value of the debt and increasing additional paid in capital. Of this, $351,000 was originally calculated in the third quarter of 2000 when the Debentures were issued. The additional amount of $489,000 was calculated in the fourth quarter of 2000 using the accounting conversion method preferred by the SEC pursuant to EITF 00-27 which clarified the method of calculating the beneficial conversion feature. The amount allocated to the beneficial conversion feature was valued using conversion method (ii) from above as of the date of the transaction as it was determined to be the most beneficial to the holders of the Debentures. This amount was expensed over the initial 90-day non-convertible period. For the year ended December 31, 2000, the Company recorded a charge of $898,000 (including $190,223 for the cumulative effect of a change in accounting principle noted above) due to amortization of the beneficial conversion feature, warrant costs and original issue discount/debt issuance costs associated with the Company's August 2000 issuance of $3,250,000 3% Senior Subordinated Convertible Debentures.

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

On April 5, 2000, the Company borrowed $2,447,000, net of related costs, under a mortgage agreement on its West Bridgewater, MA facility, of which approximately $2,315,000 remains outstanding as of December 31, 2003. The Company used the funds to reduce the outstanding balance of its existing line of credit. The principal amount of the note issued in connection with the mortgage is due on March 31, 2010. During the first five years the note carries an interest rate of 9.75%; after five years the rate charged will be .75% greater than the Corporate Base Rate then in effect. The mortgage precludes the payment of dividends on the Company's common stock and contains certain other restrictive covenants. Under this mortgage agreement the Company is subject to certain financial covenants. The Company failed to meet its debt service coverage covenant for the prior year ended December 31, 2002, but in early 2003 the financial institution waived that default and the Company's other defaults relating to reports and the termination of the Company's former chairman and chief executive officer. 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. Monthly payments on this mortgage are based on a 20 year amortization schedule with a balloon payment representing the remaining balance due in full on March 10, 2010. The mortgage is collateralized by the Company's West Bridgewater, MA facility, which has a net book value of $2,045,000 at December 31, 2003. Future principal payments due on the Company's mortgage agreement are approximately $54,000, 62,000, $69,000, $76,000 and $84,000 for each of the years ended December 31, 2004, 2005, 2006, 2007, and 2008, respectively.

(8) Retirement Plan

In January 1993, the Company adopted a retirement savings plan for its employees, which has been qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the plan through payroll deductions within statutory limitations and subject to any limitations included in the plan. Company contributions are made at the discretion of management. As of December 31, 2001, no such contributions had been made, however, commencing in 2002, the Company formally adopted and implemented a limited matching contribution program. During 2003, 2002 and 2001 the Company recognized administrative expense of approximately $21,000, $22,000, and $23,000, respectively, in connection with the plan.

(9) Income Taxes

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

	2003	2002	2001
Current (benefit) provision: federal	$ —	$ —	$ —
Current provision: state	3,430	2,936	15,678
Total current provision	3,430	2,936	15,678
Deferred provision: federal	—	—	—
Deferred provision: state	—	—	—
Total deferred provision	—	—	—
Total provision for income taxes from continuing operations	$ 3,430	$ 2,936	$ 15,678

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

	2003	2002
Current deferred taxes:		
Inventory	$ 311,889	$ 391,563
Accounts receivable allowance	49,639	46,998
Technology licensed	209,352	231,984
Other accruals	234,218	365,960
Less: valuation allowance	(805,098)	(1,036,505)
Total current deferred tax assets	—	—
Long term deferred taxes:		
Accelerated tax depreciation	239,156	53,868
Goodwill and intangibles	418,372	479,200
Tax credits	450,960	484,103
Operating loss carryforwards	2,562,139	1,844,460
Less: valuation allowance	(3,670,627)	(2,861,631)
Total long term deferred tax assets (liabilities), net	—	—
Total net deferred tax assets	$ —	$ —

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

The Company had net operating loss carryforwards for federal income tax purposes of approximately $5,400,000 and $3,500,000 at December 31, 2003 and 2002, respectively. These net operating loss carryforwards expire at various dates from 2011 through 2023. Included in this number are remaining loss carryforwards of approximately $1,350,000 that were obtained through the acquisition of BioSeq, Inc. These carryforwards expire from 2011 through 2018. The Company had net operating loss carryforwards for state income tax purposes of approximately $11,700,000 and $10,500,000 at December 31, 2003 and 2002, respectively. These net operating loss carryforwards expire at various dates from 2004 through 2023. Included in this number are loss carryforwards of

approximately $2,000,000 that were obtained through the acquisition of BioSeq, Inc. These carryforwards expire from 2011 through 2018.

As of December 31, 2003, the Company had approximately $78,000 of alternative minimum tax credits, which do not expire, and $372,000 of federal research credits, which expire from 2010 to 2023. Included in the net operating loss and credit carryforwards discussed above is a deferred tax asset of approximately $265,000 reflecting the benefit of deductions from the exercise of stock options ($53,088 was utilized in year 2003 in conjunction with the filing of prior year state income tax returns and was recorded to additional paid-in capital). Any future benefits from this deferred tax asset will be recorded to additional paid-in capital when realized.

The Company's effective income tax rate from continuing operations for the years ended December 31, 2003, 2002 and 2001 differs from the statutory federal income tax rate as follows:

	2003	2002	2001
Federal tax(benefit) provision rate	(34)%	(34)%	(34)%
State tax(benefit) provision, net of federal benefit	(4)%	(4)%	(4)%
Non-cash deductions and other permanent items, net	1%	2%	(10)%
Valuation allowance	37%	36%	50%
Effective income tax (benefit) provision rate from continuing operations	0%	0%	2%

The Company's federal income tax returns for fiscal years 1997 and 1998 were examined by the Internal Revenue Service. The Company agreed to a settlement of the audit covering these years. The final computation of the assessment due, including the effect on the associated state income tax returns for those years, did not have an adverse effect on the accompanying consolidated financial statements as the Company utilized certain net operating loss carryforwards and carrybacks to offset the federal income tax assessment.

(10) Commitments and Contingencies

Leases

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; see also Note 13 of Notes to Consolidated Financial Statements hereunder. 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 May 2000, the Company acquired laboratory equipment pursuant to a three-year capital lease at 12% financing, resulting in total payments of approximately $115,000 over the life of the lease agreement; this lease expired in June 2003.

At December 31, 2003, future minimum lease payments under non-cancelable leases, excluding discontinued operations, is as follows:

Year Ended	Operating Leases
2004	$ 1,229,000
2005	961,000
2006	933,000
2007	541,000
2008 and thereafter	—
Total minimum lease payments	$ 3,664,000

The Company entered into a non-cancelable sublease agreement with a third party that expired January 2002. Rent expense, net of sublease income consisted of the following:

	2003	2002	2001
Basic expense	$ 1,179,000	$ 1,111,000	$ 1,274,000
Sublease income	—	(14,000)	(169,000)
Rent expense, net	$ 1,179,000	$ 1,097,000	$ 1,105,000

In addition, as discussed further in Note 2, as of December 31, 2003, the Company was subject to future minimum facility lease payments in connection with the discontinued operations of its clinical laboratory segment of $161,000 and $94,000 in 2004 and 2005, respectively. The Company included an estimate of this remaining lease commitment in 2001 as part of the calculation of the gain on the sale of certain assets from the clinical laboratory segment; see also Note 13 of Notes to Consolidated Financial Statements.

The Company's California and Maryland facility leases include scheduled base rent increases over the term of the lease. The amount of base rent payments is charged to expense using the straight-line method over the term of the lease. As of December 31, 2003 and 2002, the Company has recorded a long-term liability of $306,000 and $357,000, ($330,000 and $356,000 including the current portion), respectively to reflect the excess of rent expense over cash payments since inception of the lease. In addition to base rent, the Company pays a monthly allocation of the operating expenses and real estate taxes for the California and Maryland facilities. See also Note 13 of Notes to Consolidated Financial Statements hereunder.

Royalty Commitments

The Company acquired in 1998 all the remaining common stock outstanding 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 the Company utilizing PCT. The Company announced the availability of its PCT products for commercial sale in the latter part of year 2002. Included in long-term liabilities at December 31, 2003 and 2002 are future minimum royalty payments of approximately $0 and $0, respectively, payable to the former owners of BioSeq, Inc. Minimum royalty payment requirements ceased in the fourth quarter of 2003 in accordance with contractual provisions.

Guarantees

See Note 12 hereunder for further discussion of the Company's limited guaranty and pledge agreement of a $1,000,000 interest bearing deposit at a financial institution to provide additional security for loans in the aggregate original amount of $2,418,000 from the financial institution to an entity controlled by the former Chief Executive Officer of the Company; this guarantee was met in January 2003. In addition, BBI Clinical Laboratories, Inc., a discontinued operation, operated from a 15,000 square foot facility in New Britain CT pursuant to a lease which expires in July 2005 and which was guaranteed by the Company. In connection with the Company's decision to exit this business segment, the Company has assumed the obligation to make the remaining lease payments, which is included in the Company's estimate of remaining liabilities associated with discontinued operations. See Notes 2 and 13 of Notes to Consolidated Financial Statements.

Indemnifications

In conjunction with certain transactions, the Company has agreed to indemnify the other parties with respect to certain liabilities related to the operation of the business. The scope and duration of such indemnity obligations vary from transaction to transaction. Where

appropriate, an obligation for such indemnifications is recorded as a liability. Generally, a maximum obligation cannot be reasonably estimated. Other than obligations recorded as liabilities at the time of divestiture, historically the Company has not made significant payments for these indemnifications. The Company believes the estimated fair value of these agreements is minimal. Any indemnification agreements are

grandfathered under the provisions of FIN No. 45 as they were in effect prior to December 31, 2002. The Company has no liabilities recorded for these agreements as of December 31, 2003 and 2002.

Other Contingencies

Various claims have been or may be asserted against the Company in the ordinary course of business. In certain instances, the amounts claimed or alleged may be significant. While it is possible that the Company's results of operations and/or liquidity could be materially affected by these contingent liabilities, based upon information currently available, management believes that resolution of any of the following outstanding claims will not have a material adverse impact on the financial position of the Company.

Licensing Agreements/Customer Claims

Subsequent to December 31, 2003, the Company has received unrelated communications from three parties relative to licensing, royalty and product performance issues. One party has requested additional information to determine whether the Company may owe additional royalties on products sold under a patent license agreement; the Company believes it has made all required royalty payments under its patent license agreement with this entity. Another party has alleged that certain products sold by the Company used component materials patented by that third party. A customer has alleged that the Company supplied defective products that were subsequently incorporated into the customer's end user products that were recalled. The Company is in the process of investigating and gathering additional information in order to respond to these inquiries. While the Company cannot estimate the amount of a loss, if any, associated with the resolution of these allegations, the Company disputes all of these allegations and intends to vigorously pursue all defenses available to the Company.

Environmental Matters

The Company has received correspondence addressed to Source Scientific, Inc. originating from the U.S. Environmental Protection Agency ("EPA"). In 1997, the Company acquired certain assets and liabilities of Source Scientific, Inc. The correspondence identifies Source Scientific, Inc. as having a potential liability for waste disposal by a purported predecessor entity. The Company has not yet determined if it actually has liability for this matter, however should the Company and the EPA agree on resolution of this matter, it is estimated that such costs could range from a minimal amount up to $42,000.

(11) Stockholders' Equity

Preferred Stock

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

Common Stock

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

Shareholders Purchase Rights Plan

On March 3, 2003, the Company's Board of Directors adopted a shareholder purchase rights plan ("the Rights Plan") and declared a distribution of one Right for each outstanding share of the Company's Common Stock to shareholders of record at the close of business on March 21, 2003. Initially, the Rights will trade automatically with the Common Stock and separate Right Certificates will not be issued. The Rights Plan is designed to deter coercive or unfair takeover tactics and to ensure that all of the Company's shareholders receive fair and equal treatment in the event of an unsolicited attempt to acquire the Company. The Rights Plan was not adopted in response to any effort to acquire the Company, and the Board is not aware of any such effort. The Rights will expire on February 27, 2013 unless earlier redeemed or exchanged. Each Right entitles the registered holder, subject to the terms of a Rights Agreement, to purchase from the Company one one-thousandth of a share of the Company's Series A Junior Participating Preferred Stock at a purchase price of $45.00 per one one-thousandth of a share, subject to adjustment. In general, the Rights will not be exercisable until a subsequent distribution date which will only occur if a person or group acquires beneficial ownership of 15% or more of the Company's Common Stock or announces a tender or exchange offer that would result in such person or group owning 15% or more of the Common Stock. With respect to any person or group who currently beneficially owns 15% or more of the Company's Common Stock, the Rights will not become exercisable unless and until such person or group acquires beneficial ownership of additional shares of Common Stock.

Subject to certain limited exceptions, if a person or group acquires beneficial ownership of 15% or more of the Company's outstanding Common Stock or if a current 15% beneficial owner acquires additional shares of Common Stock, each holder of a Right (other than the 15% holder whose Rights become void once such holder reaches the 15% threshold) will thereafter have a right to purchase, upon payment of the purchase price of the Right, that number of shares of the Company's Common Stock which at the time of such transaction will have a market value equal to two times the purchase price of the Right In the event that, at any time after a person or group acquires

15% or more of the Company's Common Stock, the Company is acquired in a merger or other business combination transaction or 50% or more of its consolidated assets or earning power are sold, each holder of a Right will thereafter have the right to purchase, upon payment of the purchase price of the Right, that number of shares of common stock

of the acquiring company which at the time of such transaction will have a market value of two times the purchase price of the Right.

The Board of Directors of the Company may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of Common Stock per Right (subject to adjustment). At any time prior to the time any person or group acquires 15% or more of the Company's Common Stock, the Board of Directors of the Company may redeem the Rights in whole, but not in part, at a price of $0.001 per Right.

Employee Stock Purchase Plan

In July 1999, the Company's Board of Directors and shareholders approved the 1999 Employee Stock Purchase Plan. The Company adopted this plan, which allows eligible employees to purchase shares of the Company's stock at 85% of market value as determined at the beginning and the end of the offering period. A total of 250,000 shares have been reserved for this plan. As of December 31, 2003, 45,601 shares had been issued under this plan.

Options and Warrants

In 1987, the Company's Board of Directors adopted the 1987 Non-Qualified Stock Option Plan. The purpose of the 1987 Non-Qualified Stock Option Plan was to provide an opportunity for employees, officers, directors and consultants employed by or affiliated with the Company or any of its subsidiaries to acquire stock in the Company, to provide increased incentives to such persons to promote the success of the Company's business and to encourage such persons to become affiliated with the Company through the granting of options to acquire its capital stock. A total of 897,600 shares of common stock had been reserved for issuance under the 1987 Non-Qualified Stock Option Plan. The 1987 Non-Qualified Stock Option Plan terminated on December 16, 1997. As of December 31, 2003, a total of 2,250 options granted remained outstanding under the 1987 Non-Qualified Stock Option Plan.

In 1994, the Company's Board of Directors and shareholders approved the adoption of the Employee Stock Option Plan (referred to herein as the "Employee Stock Option Plan"). The purpose of the Employee Stock Option Plan is to provide increased incentives to employees of the Company to remain affiliated with the Company, to promote the success of the Company's business and to associate more closely the interests of such persons with those of the Company through the granting of options to acquire the capital stock of the Company. Under the Employee Stock Option Plan, as amended in July 1999, an aggregate of 2,000,000 shares of common stock have been authorized for issuance upon exercise of non-qualified and incentive stock options granted under the Plan. Options may be granted to those employees of the Company who are employed a minimum of 20 hours per week.

In 1999, the Board of Directors and shareholders approved the adoption of the 1999 Non-Qualified Stock Option Plan which authorizes the issuance of up to 500,000 shares of common stock upon exercise of non-qualified stock options. The purpose of the 1999 Non-Qualified Stock Option Plan is to attract and retain employees, directors, advisors and consultants and provide an incentive for them to assist the Company to achieve long-range performance goals, and to enable them to participate in the long-term growth of the Company. Options under the 1999 Non-Qualified Stock Option Plan may be granted to employees, directors, advisers and consultants of the Company, capable of contributing significantly to the successful performance of the Company.

The Employee Stock Option Plan and the 1999 Non-Qualified Stock Option Plan are administered by a committee of the Board of Directors. The exercise price of options granted under these plans generally equals the fair market value of the stock at grant date. Generally, options become exercisable at the rate of 25% at the end of each of the four years following the anniversary of the grant. Options expire ten years from the date of grant, or 30 days from the date the grantee's affiliation with the Company terminates.

At December 31, 2003, 1,764,163 shares were reserved for incentive stock options under the Employee Stock Option Plan, of which 967,788 are available for future grants; this plan terminates on June 29, 2004. At December 31, 2003, there were 487,250 shares reserved under both the 1987 Non-Qualified Stock Option Plan, which terminated in 1997, and the 1999 Non-Qualified Stock Option Plan of which 44,800 are available for future grants.

In August 1999, the Company sold 500,000 warrants to purchase the Company's stock to Paradigm Group, a private investment company. The private placement consisted of warrants to purchase 400,000 shares of common stock at a purchase price of $4.25 and 100,000 shares of common stock at a purchase price of $5.25. Paradigm Group paid the Company $50,000 for the warrants. In addition, National Securities received warrants to purchase 40,000 shares of common stock with a purchase price of $4.25, warrants to purchase 10,000 shares of common stock with a purchase price of $5.25, and warrants to purchase 25,000 shares of common stock with a purchase price of $8.00, as a transaction fee. In February 2000, the Company received notice that Paradigm Group, LLC exercised all of their warrants to purchase the Company's common stock. The holders of the warrants were required to pay the purchase price when the registration of the underlying shares became effective, which was in December 2000. In August 2000, the Company received a summons and complaint from Paradigm Group, LLC naming the Company as a defendant. The suit, filed in the Circuit Court of Cook County, Illinois, alleged breach of contract claims and fraud against the Company in connection with the sale by the Company to the Paradigm Group, LLC of the above warrants, the exercise of those warrants by Paradigm Group, LLC and a delay in the registration of those shares with the U. S. Securities and Exchange Commission. In December 2000, Paradigm Group, LLC withdrew this lawsuit. In the fourth

quarter of 2000, the Company expensed approximately $265,000 of costs related to these warrants and the registration of the underlying shares. On June 15, 2001, the Company and Paradigm Group, LLC entered into an agreement to permanently settle their disputes. Under the terms of the agreement, Paradigm Group, LLC rescinded their exercise of the common stock purchase warrants, which have since expired, and the Company retained the 500,000 shares associated with the warrants issued in that private placement. These shares were included in the total shares outstanding as well as in the calculation of earnings (loss) per share from February 17, 2000 (the date of exercise) through June 15, 2001 (the date of the agreement). As of September 30, 2001, these shares were cancelled by the Company.

In November 1999, the Company sold 29,155 equity units to MDBio, Inc. a Maryland not-for profit corporation. Each equity unit consisted of one share of common stock and a warrant to purchase one share of common stock with an exercise price of $10.00 per share. The common stock was issued during 2003. MDBio paid the Company $175,000 for the equity units in 1999. The associated shares were issued to MDBio in 2003, however, the related warrants expired unexercised at the close of business September 30, 2003.

On September 30, 1998 the Company acquired the remaining outstanding common stock (approximately 81%) of BioSeq, Inc., a development stage company with patent pending technology based on pressure cycling technology for $879,000 in cash (net of cash acquired of $121,000). In connection with the Company's acquisition of BioSeq, Inc., the Company issued warrants to purchase 100,000 shares of the Company's common stock at a purchase exercise price of $2.50 per share (subject to annual increases). None of these warrants remain outstanding as of December 31, 2003.

On August 25, 2000, the Company entered into Securities Purchase Agreements providing for the issuance of $3,250,000 (face value) 3% Senior Subordinated Convertible Debentures due August 25, 2003. As of December 31, 2003, none of the 3% Senior Subordinated Convertible Debentures were outstanding. In connection with this transaction, the Company issued warrants, to purchase up to 135,556 shares of the Company's common stock at an exercise price of $3.60 per share. As of December 31, 2003, warrants to purchase 135,556 shares of common stock remained outstanding. These warrants expire in August 2005.

The average fair value of options granted during 2003, 2002 and 2001 is estimated as $1.81, $1.97 and $1.75, respectively.

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

	Stock Options		Warrants		Total	
	Shares	Weighted Average price per share	Shares	Weighted Average price per share	Shares	Exercisable
Balance outstanding, 12/31/2000:	1,245,178	$ 3.06	457,730	$ 6.81	1,702,908	1,068,403
Granted	341,900	2.57	—	—	341,900	
Exercised	(162,750)	2.43	(829)	2.75	(163,579)	
Cancelled	(337,041)	2.94	(210,000)	9.80	(547,041)	
Balance outstanding, 12/31/2001:	1,087,287	3.02	246,901	4.13	1,334,188	857,574
Granted	608,650	2.89	—	—	608,650	
Exercised	(42,944)	2.89	(5,000)*	2.74	(47,944)	
Cancelled	(257,306)	2.76	(10,000)	4.25	(267,306)	
Balance outstanding, 12/31/2002:	1,395,687	3.01	231,901	4.40	1,627,588	789,623
Granted	91,700	2.73	—	—	91,700	
Exercised	—	0.00	0	0.00	—	
Cancelled	(241,562)	3.25	(96,345)	5.58	(337,907)	
Balance outstanding, 12/31/2003:	1,245,825	$ 2.94	135,556	$ 3.60	1,381,381	844,970

* Includes a net exercise of 5,000 warrants for which 924 shares of the Company's common stock were issued.

The following table summarizes information concerning options outstanding and exercisable as of December 31, 2003:

Range of Exercise Prices	Weighted Average Remaining Life	Options Outstanding		Options Exercisable	
		Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$ — - $ 2.50	7.0	239,450	$ 2.50	154,225	$ 2.50
2.51 - 3.00	8.6	478,100	2.68	195,513	2.67
3.01 - 3.50	6.1	424,875	3.18	266,001	3.22
3.51 - 4.00	6.1	22,400	4.00	17,300	4.00
4.01 - 4.50	5.6	81,000	4.31	76,375	4.30
0.00 - 4.50	7.2	1,245,825	2.94	709,414	3.05

The total number of options exercisable as of December 31, 2003, 2002 and 2001 was 709,414, 557,722 and 610,673, respectively. The weighted average exercise prices of options exercisable as of December 31, 2003, 2002 and 2001 were $3.05, $3.25 and $3.13 respectively.

(12) 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 Boston Biomedica 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 the loan was repaid in full with a portion of the proceeds of the loans described in the next sentence. The Company's loan was replaced by the Company's limited guaranty and 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. Such collateral originally included certain of his real property and all of his Company common stock. 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 Company common stock 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 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. The Company continues to maintain its junior interest in collateral pledged by Mr. Schumacher to the financial institution. As of December 31, 2003, the remaining collateral includes certain of Mr. Schumacher's Company common stock. The Company reflected the $1,000,000 pledge as restricted cash on its balance sheet as of December 31, 2002 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 stockholders' equity.

As of December 31, 2003, the Company evaluated the recoverability of the $1,000,000 loan receivable from its former Chairman and Chief Executive Officer. The Company's review includes an evaluation of the remaining collateral associated with the loan. The Company maintains a junior interest in this collateral. The remaining collateral consists of common stock of the Company. When considering the adequacy of the collateral, 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 the 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.

(13) Subsequent Events

On February 5, 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 a covenant regarding a minimum debt service coverage ratio, and provides certain restrictions on the payments of dividends and incurring additional debt.

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 Agreement, Mr. Schumacher will continue in an advisory role directing the Company's Pressure Cycling Technology (PCT) and BBI Source Scientific activities, and the Company's interest in Panacos Pharmaceuticals, Inc. PCT is the Company's novel and patent protected technology that uses cycles of hydrostatic pressure to control biomolecular interactions; BBI Source Scientific, Inc. is the Company's laboratory instrument subsidiary, which developed and manufactures the PCT Barocycler instrument; and Panacos is a privately-held, anti-viral drug discovery company spun off from BBI in 2000. 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.

On March 1, 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 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. This lease is subject to cancellation at the sole option of the Company on or before April 30, 2004 without penalty.

On March 4, 2004, the Company entered into a lease termination agreement with an existing landlord relative to a facility previously occupied by BBI Clinical Laboratories, Inc., a discontinued operation of the Company and formerly a wholly-owned subsidiary of the Company. The agreement calls for a series of reduced payments over the next nine months in return for the Company vacating the facility on or before May 31, 2004.

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

2003	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
Total revenue	$ 5,643	$ 6,023	$ 5,829	$ 5,801
Gross profit	2,186	2,146	2,022	2,077
(Loss) from continuing operations	(254)	(225)	(356)	(454)
(Loss) income from discontinued operations	—	—	—	—
Net income (loss)	$ (254)	$ (225)	$ (356)	$ (454)
(Loss) income per share from continuing operations, basic & diluted	(0.04)	(0.03)	(0.05)	(0.07)
Income per share from discontinued operations, basic & diluted	—	—	—	—
Net income (loss) per share, basic & diluted	$ (0.04)	$ (0.03)	$ (0.05)	$ (0.07)

2002	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
Total revenue	$ 4,953	$ 5,856	$ 5,876	$ 6,080
Gross profit	1,885	2,378	2,018	2,221
(Loss) income from continuing operations	(887)	(294)	(567)	35
Income from discontinued operations	—	—	225	—
Net income (loss)	$ (887)	$ (294)	$ (342)	$ 35
Income (loss) per share from continuing operations, basic & diluted	(0.14)	(0.04)	(0.08)	0.01
Income per share from discontinued operations, basic & diluted	—	—	0.03	—
Net income (loss) per share, basic & diluted	$ (0.14)	$ (0.04)	$ (0.05)	$ 0.01

INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying consolidated balance sheet of Boston Biomedica, Inc. and Subsidiaries (the "Company"), as of December 31, 2003 and the related consolidated statements of operations, changes in stockholders' equity and cash flows and the financial statement schedule listed in Item 15(a)2 for the year then ended. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatements. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Boston Biomedica, Inc. and Subsidiaries as of December 31, 2003, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule referred to above when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information required to be included therein.

WEINBERG & COMPANY, P.A.

Boca Raton, Florida
March 4, 2004

Report of Independent Auditors

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

In our opinion, the consolidated financial statements listed in the index appearing under Item 15 (a) (1) of this Form 10-K, present fairly, in all material respects, the financial position of Boston Biomedica, Inc. and its subsidiaries at December 31, 2002, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15 (a) (1) presents fairly, in all material respects, the information set forth therein for each of the two years in the period ended December 31, 2002 when read in conjunction with the related consolidated financial statements. These financial statements and the financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 1 of Notes to Consolidated Financial Statements, in 2002 the Company adopted Financial Accounting Standards Board Statement of Financial Accounting Standards No. 142, "Goodwill and Intangible Assets."

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 27, 2003

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

On August 22, 2003, PricewaterhouseCoopers LLP resigned as the independent accountants of the Company, effective August 22, 2003. The reports of PricewaterhouseCoopers LLP on the Company's consolidated financial statements for each of the fiscal years ended December 31, 2001 and December 31, 2002 did not contain an adverse opinion or disclaimer of opinion nor were they qualified or modified as to uncertainty, audit scope or accounting principles. During the fiscal years ended December 31, 2001 and December 31, 2002 and through August 22, 2003, there were no disagreements with PricewaterhouseCoopers LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of PricewaterhouseCoopers LLP, would have caused PricewaterhouseCoopers LLP to make reference to the subject matter of the disagreement in connection with their report on the financial statements for such years. In addition, during the fiscal years ended December 31, 2001 and December 31, 2002 and through August 22, 2003, there were no reportable events as defined in Item 304(a)(1)(v) of Regulation S-K.

On November 5, 2003, 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. During the fiscal years ended December 31, 2001 and December 31, 2002 and through the date hereof, neither the Company nor anyone on its behalf consulted with Weinberg & Company with respect to any matters or events, including any matters or events set forth and described in Items 304(a)(2)(i) and (ii) of Regulation S-K.

ITEM 9A. CONTROLS AND PROCEDURES.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our President (Principal Executive Officer and Principal Financial Officer), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of December 31, 2003, we carried out an evaluation, under the supervision and with the participation of our management, including our President (Principal Executive Officer and Principal Financial Officer) of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934. Based upon that evaluation, our President (Principal Executive Officer and Principal Financial Officer) concluded that our disclosure controls and procedures are effective in enabling us to record, process, summarize and report information required to be included in our periodic

SEC filings within the required time period.

There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 PGBP Pharmaceuticals, a small molecule discovery company, Ultra Imaging, Inc., a handheld imaging device company, and Immune Cell Therapy, Inc., a thrombolytic therapy 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. Mr. Vogel is 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 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*."

ITEM 11. EXECUTIVE COMPENSATION

The following Summary Compensation Table sets forth the compensation during the last three fiscal years of (i) each person who served as Chief Executive Officer during fiscal year 2003, and (ii) the four other most highly compensated Executive Officers of the Company who were serving as Executive Officers at the end of fiscal 2003 and whose total annual salary and bonus, if any, exceeded

$100,000 for services in all capacities to the Company during the fiscal year ended December 31, 2003 (collectively, the "Named Executive Officers").

Summary Compensation Table

Name and Principal Position	Fiscal Year Ended	Annual Compensation			Long Term Compensation	All Other Compensation ($) (6)
		Salary ($)	Bonus ($)	Other Annual Compensation	Securities Underlying Stock Options (#)	
Richard T. Schumacher,	12/31/03	$ 30,769(2)	—	$ 123(5)	-0-	$ 5,731(3)(4)
Former Chief Executive	12/31/02	245,866	—	1,019(5)	90,000	6,616(3)(4)
Officer and Chairman	12/31/01	237,500	—	1,163(5)	40,000	7,703(3)(4)
of the Board (1) (2)						
Kevin W. Quinlan,	12/31/03	$ 194,250	—	$ 3,513(5)	-0-	$ 2,909(3)(4)
President and Chief	12/31/02	191,769	—	2,973(5)	107,000	2,909(3)(4)
Operating Officer,	12/31/01	185,000	—	3,575(5)	24,000	2,854(3)(4)
Treasurer and Director						
Mark M. Manak, Ph.D.	12/31/03	$ 147,000	—	—	-0-	$ 676(4)
Senior Vice President and	12/31/02	147,000	—	—	46,500	675(4)
General Manager, BBI	12/31/01	141,346	—	—	—	638(4)
Biotech						
Kathleen W. Benjamin	12/31/03	$ 119,538	—	—	-0-	$ 342(4)
Vice President,	12/31/02	115,508	—	—	10,000	342(4)
Human Resources and	12/31/01	102,754	—	—	6,000	212(4)
Clerk						
Richard J. D'Allessandro,	12/31/03	$ 124,917	—	—	-0-	$ 1,037(4)
Vice President, Information	12/31/02	121,964	—	—	10,000	1,037(4)
Technology	12/31/01	117,046	—	—	6,000	853(4)

(1) In 2001, the Company's Board of Directors authorized loans from the Company to Mr. Schumacher totaling $450,000. Mr. Schumacher borrowed an additional $75,000 from the Company late in 2001. In January 2002, the principal of these loans were repaid in full. The loans were replaced by the Company's pledge of a $1,000,000 interest bearing deposit at a financial institution to provide additional security for loans in the aggregate amount of $2,418,000 from the financial institution to an entity controlled by Mr. Schumacher. In January 2003, the $1,000,000 pledged to the financial institution was used to satisfy the Company's guaranty obligation to the financial institution. For a detailed description of the terms of these transactions, please see "Certain Relationships and Related Transactions" in Item 13 of this report below.

(2) On February 14, 2003, the Company announced that it had terminated Mr. Schumacher as Chairman of the Board and Chief Executive Officer. Mr. Schumacher remains a Director of the Company. The salary data presented in this chart for Mr. Schumacher covers the period January 1, 2003 through and including February 13, 2003, and excludes $41,353 of accrued vacation earned and paid subsequent to February 13, 2003. On July 9, 2003, the Company announced 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. In February 2004, this agreement was extended through December 31, 2004. For a description of the terms of the Company's consulting agreement with Mr. Schumacher including compensation arrangements and director fees, please see "Compensation of Directors" and "Board of Directors Report on Executive Compensation" hereunder and Item 13 "Certain Relationships and Related Transactions" below.

(3) Includes the value of premiums paid for term life and disability insurance policies. Included in the year 2003 amounts are the value of premiums for term life and disability insurance, respectively, for Mr. Schumacher ($4,450 and $498, respectively), and for Mr. Quinlan ($0 and $1,970, respectively). Included in the year 2002 amounts are the value of premiums for term life and disability insurance, respectively, for Mr. Schumacher ($3,382 and $1,992, respectively), and for Mr. Quinlan ($0 and $1,970, respectively).

(4) Includes the value of imputed income from group life insurance.

(5) Consists of personal use of a Company vehicle.

(6) Year 2003 compensation excludes the following amounts pursuant to Company matching contributions associated with year 2003 participation in the Company's 401K plan: Mr. Schumacher - $1,921; Mr. Quinlan - $2,062; Mr. Manak — $1,526; Ms. Benjamin - $1,237; and Mr. D'Allessandro - $928.

The following tables set forth certain information with respect to the stock options granted to and exercised by the Named Executive Officers during fiscal 2003 and the aggregate number and value of options exercisable and unexercisable held by the Named Executive Officers during fiscal 2003.

Option Grants in Fiscal Year 2003

There were no options granted by Boston Biomedica, Inc. to any of the Named Executive Officers in fiscal year 2003.

Aggregated Option Exercises in Last
Fiscal Year and Fiscal Year End Option Values

Name	Shares Acquired on Exercise (#)	Value Realized ($) (1)	Number of Securities Underlying Unexercised Options at Year End (#) (2)		Value of Unexercised In-the-Money Options at Year End ($) (3)	
			Exercisable	Un-exercisable	Exercisable	Un-exercisable
Richard T. Schumacher	—	—	42,500	87,500	$ 600	$ 600
Kevin W. Quinlan	—	—	85,000	78,500	360	360
Mark M. Manak, Ph.D.	—	—	32,625	27,375	-0-	-0-
Kathleen W. Benjamin	—	—	19,500	10,500	390	390
Richard J. D'Allessandro	—	—	13,500	10,500	390	390

(1) The "value realized" represents the excess of the fair market value over the purchase price at the time of purchase based upon the closing price of the Common Stock on the Nasdaq National Market on the date of exercise, minus the respective option exercise price. There were no Boston Biomedica, Inc. stock options exercised by the Named Executive Officers in fiscal year 2003.

(2) Includes the number of shares underlying both "exercisable" (i.e., vested) and "un-exercisable" (i.e., unvested) stock options as of December 31, 2003.

(3) The values of "in-the-money" options reflect the positive spread between the exercise price of any such existing stock options and the closing year-end per share price of the Common Stock of $2.63, as quoted on the Nasdaq National Market on December 31, 2003.

Compensation of Directors

Non-employee Directors of the Company received a quarterly stipend of $2,500, for a yearly total of $10,000 for their services in 2003. In addition, in 2003, each non-employee Director who is a member of the Audit Committee received an additional $500 per quarter for a yearly total of $2,000 and each non-employee Director who is a member of the Compensation Committee received an additional $500 per quarter for a yearly total of $2,000. As additional Director compensation in recognition of the significant additional effort and time they were required to devote to their responsibilities on the Oversight Committee, Mr. Wilson was paid $94,044, Dr. Saravis was paid $20,095 and Mr. Capitanio (a Director of the Company until October 2, 2003) was paid $3,986 for time spent (and expenses incurred) in year 2003 discharging their responsibilities for the Oversight Committee. No further payments are anticipated to members of the Oversight Committee. Each Director is eligible to receive options to purchase Common Stock under the Company's 1999 Non-Qualified Stock Option Plan. Non-employee Directors of the Company are granted a minimum of 10,000 non-qualified stock options at the start of their term of service, which generally vest over a three year period and have an exercise price equal to the fair market value of the underlying shares on the date of the grant. During the period February 13, 2003 to June 30, 2003, Mr. Schumacher received $3,777 of compensation from the Company in his role as a member of the Board of Directors during that time frame.

Effective January 1, 2004, compensation for independent members of the Board of Directors will be set at a monthly stipend of $2,000, of which $1,000 will be compensation for attending full Board meetings (whether telephonic or in-person) and $1,000 will be compensation for attending committee meetings. There will be no limit to the number of either full Board or committee meetings called, nor will any independent member receive more than $2,000 per month regardless of the number of meetings attended. It is furthermore expected that each independent Board member who is not Chairman of the Board will be Chairman of the Audit, Compensation or Scientific Advisory Board Committees. It is also expected that each independent Board member will also serve on at least one committee that they do not Chair. In addition to cash compensation, each independent member of the BBI Board of Directors will also receive a one-time grant of 10,000 fully vested, non-qualified stock options, as well as an annual grant of 5,000 fully vested, nonqualified stock options. The initial set of options will be granted as soon as feasible upon joining the Board; the annual set of options will be granted on the first business day of March each year. Cash compensation will be paid in the first payroll of each fiscal quarter.

Compensation Committee Interlocks and Insider Participation

For the fiscal year ended December 31, 2003, the Board of Directors made decisions regarding executive compensation based on the recommendations of those members of the Board of Directors who also serve on the Compensation Committee. The individuals who served on the Compensation Committee in fiscal year 2003 and who made recommendations to the full Board of Directors consisted of Richard T. Schumacher, Dr. Calvin A. Saravis, William A. Wilson, and Francis E. Capitanio each of whom has received options to purchase Common Stock. Mr. Schumacher served as the Chief Executive Officer and Chairman of the Board of the Company in fiscal year 2002 and through February 13, 2003. Effective February 13, 2003, Mr. Capitanio replaced Mr. Schumacher as a member of the Compensation Committee; Mr. Capitanio did not stand for reelection as a member of the Board of Directors and accordingly, his term of office expired on October 2,, 2003. Mr. Wilson resigned as a Director of the Company on October 3, 2003. Neither Dr. Saravis, Mr. Capitanio nor Mr. Wilson is or was a former nor current officer nor employee of the Company.

In fiscal 2003, the members of the Compensation Committee did not meet formally as a committee, but rather made recommendations regarding executive compensation at meetings of the full Board of Directors. The full Board of Directors then made final decisions regarding executive compensation. Neither Mr. Schumacher nor Mr. Quinlan participated in any vote or deliberations establishing their own compensation.

Board of Directors Report on Executive Compensation

As described above under the heading "Compensation Committee Interlocks and Insider Participation", for the fiscal year ended December 31, 2003, the full Board of Directors made decisions regarding executive compensation based on the recommendations of those members of the Board of Directors who serve on the Compensation Committee. These recommendations were made at meetings of the full Board of Directors. The Compensation Committee did not hold any formal meetings during fiscal year 2003. These individuals made recommendations and presentations to the full Board of Directors on compensation levels, including salaries, incentive plans, benefits and overall compensation for officers and Directors and issuance of stock options to officers, Directors and employees. Subsequent to the recommendation of these individuals, the Board of Directors then voted on these proposals.

The primary objective in determining the type and amount of Executive Officer compensation is to provide a level of base compensation which allows the Company to attract and retain superior talent. The Board of Directors endeavors to align the Executive Officer's interests with the success of the Company through participation in the Company's employee stock option plan, which provides the Executive Officer with the opportunity to build a substantial ownership interest in the Company.

The compensation of Executive Officers includes cash compensation, the grant of stock options, and participation in benefit plans generally available to employees. In determining base salary, consideration is given to executive compensation for comparably sized companies as well as the individual experience and performance of each Executive Officer and the performance of the Company generally. Base salary recommendations are at a level believed to be comparable to cash compensation of officers with similar responsibilities in similarly situated corporations.

Each of the Executive Officers, including Mr. Schumacher through February 13, 2003,,and all full-time employees are eligible to receive grants of options under the Company's employee stock option plans. The employee stock option plans are used to provide incentives to officers and employees and to associate more closely the interests of such persons with stockholders' interests and the long-term success of the Company. In determining the number of options to be granted to each Executive Officer or employee, a subjective determination is based on factors such as the individual's level of responsibility, performance, and number of options held. During fiscal 2003, no options were granted to the Named Executive Officers under the employee stock option plans.

In 2002, the Company's Board of Directors established a target bonus program for Mr. Schumacher and Mr. Quinlan. There were no bonuses accrued nor paid in year 2003 pursuant to this program. During the period January 1, 2003 through February 13, 2003, Mr. Schumacher, the Company's Chief Executive Officer during that period, received salary of $30,769 which excluded accrued vacation earned to and including February 13, 2003 in the amount of $41,353. The Board of Directors believes that his annualized base compensation ($250,000) was comparable to the cash compensation of Chief Executive Officers of comparable companies. Mr. Schumacher was not granted any stock options in fiscal year 2003 by the Company.

On July 9, 2003, the Company announced that Mr. Schumacher, a Director of the Company, 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.

During the period January 1, 2003 through February 13, 2003, Mr. Schumacher, the Company's Chief Executive Officer during that period, received a base annualized salary of $250,000 plus $41,353 of accrued vacation pay remitted to Mr. Schumacher in late February 2003 subsequent to his termination as Chairman and Chief Executive Officer on February 13, 2003. The Board of Directors believes this annualized compensation was comparable to the cash compensation of Chief Executive Officers of comparable companies.

The Compensation Committee, in determining the CEO's and the President's compensation, reviews compensation for CEOs and Presidents of publicly-held companies of similar size, including those in business of detection and treatment of infectious diseases and similar businesses, their individual performance against quantitative and qualitative goals, and our Company's performance.

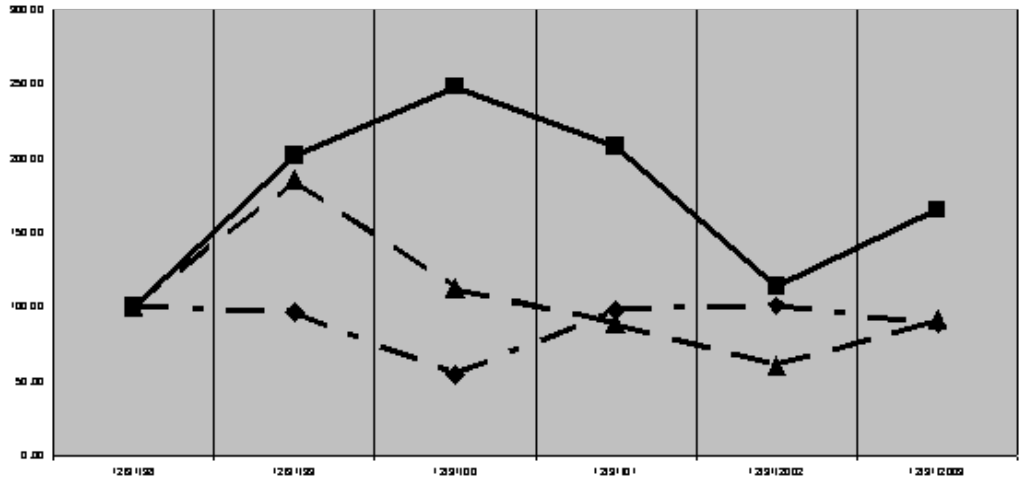
Section 162(m) of the Internal Revenue Code generally disallows a tax deduction for compensation over $1,000,000 paid by a public company to its chief executive officer and its four other most highly compensated executive officers. Qualifying "performance-based" compensation is not subject to the deduction limit if specified requirements are met. The Board of Directors generally intends to structure stock options granted to its executive officers in a manner to qualify as performance-based compensation under Section 162(m). While the Board of Directors does not currently intend to qualify cash compensation as performance-based compensation for purposes of Section 162(m), it will continue to monitor the impact of Section 162(m) on the Company.

Board of Directors

R. Wayne Fritzsche
Dr. Calvin A. Saravis
J. Donald Payne
P. Thomas Vogel
Richard T. Schumacher
Kevin W. Quinlan

Performance Graph

The following graph compares the change in the Company's cumulative total stockholder return from December 31, 1998 to December 31, 2003, which includes the last trading day of fiscal 2003, with the cumulative total return on the Nasdaq Stock Market Index (Composite) and the Nasdaq Stock Market Index (Biotechnology) (SIC 2830-2839 U.S. and Foreign) for that period.



Legend

Symbol	Index Description	12/31/98	12/31/99	12/31/00	12/31/01	12/31/02	12/31/03
- — ¨- —	Boston Biomedica, Inc.	100.00	96.83	54.73	98.35	101.04	88.58
——□——	Nasdaq Stock Market (Biotechnology)	100.00	201.64	248.00	207.81	113.62	165.59
—D—	Nasdaq Stock Market (Composite)	100.00	185.59	112.67	88.95	60.91	91.37

Assumes $100 invested on December 31, 1998 in the Company's Common Stock, the Nasdaq Stock Market Index (Biotechnology) and the Nasdaq Stock Market Index (Composite), and the reinvestment of any and all dividends.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth certain information as of December 31, 2003 concerning beneficial ownership of Common Stock by each Director and each Named Executive Officer in the Summary Compensation Table under "Executive Compensation" below, all Executive Officers and Directors as a group, and each person known by the Company to be the beneficial owner of 5% or more of the Company's Common Stock. Unless otherwise noted, each person identified below possesses sole voting power and investment power with respect to the shares listed. This information is based upon information received from or on behalf of the named individuals.

Name *	Number of Shares of Common Stock Beneficially Owned	Percent of Class
Richard T. Schumacher (1) (5) * 65 Black Pond Road Taunton, MA 02780	737,797	10.68 %
Kevin W. Quinlan (1)	129,744	1.87 %
Mark M. Manak, Ph.D. (1)(2)	65,257	**
Kathleen W. Benjamin (1)	22,416	**
Richard J. D'Allessandro (1)	15,750	**

Calvin A. Saravis, Ph.D. (1)	39,290	**
R. Wayne Fritzsche (1)	3,000	**
J. Donald Payne (1)	-0-	**
P. Thomas Vogel (1)	-0-	**
All Executive Officers and Directors as a group (11 Persons)(1)(2)	1,092,653	15.25 %
Richard P. Kiphart (3) * c/o William Blair & Company, L.L.C. 222 West Adams Street Chicago IL 60606	1,542,989 (3)(4)	22.60 %
Shoreline Micro-Cap Fund I LP (4)* c/o William Blair & Company, L.L.C. 222 West Adams Street Chicago, IL 60606	365,613 (4)	5.35 %

* Address provided for beneficial owners of more than 5% of the Common Stock.

** Less than 1% of the outstanding Common Stock.

(1) Includes the following shares issuable upon exercise of options exercisable within 60 days after December 31, 2003: Mr. Schumacher — 57,500; Mr. Quinlan — 98,000; Dr. Manak —36,750; Ms. Benjamin — 20,750; Mr. D'Allessandro —14,750; Dr. Saravis — 28,334; Mr. Fritzsche —3,000; Mr. Payne — 0; Mr. Vogel — 0; all other Executive Officers —56,750. 629,957 of Mr. Schumacher's shares of stock have been pledged to a financial institution. Please see Item 13, Certain Relationships and Related Transactions.

(2) Includes 4,000 shares held of record by Dr. Manak's daughter and 24,507 shares held in Dr. Manak's name.

(3) Includes 90,000 shares held by Rebecca Kiphart (Mr. Kiphart's daughter), and also currently exercisable warrants (expiring August 2005) to purchase 27,734 shares of common stock. This amount also includes 365,613 shares beneficially owned by Shoreline Micro-Cap Fund I LP described in Note 4 below.

(4) Includes 357,791 shares, and also currently exercisable warrants (expiring August 2005) to purchase 7,822 shares of common stock, held by Shoreline Micro-Cap Fund I LP, a fund of which Mr. Kiphart serves as general partner and has the sole power to vote and dispose or direct the disposition of shares held by Shoreline Micro-Cap Fund I LP.

(5) Includes 20,473 shares and 21,917 options held by Mr. Schumacher's spouse.

We maintain a number of equity compensation plans for employees, officers, directors and other entities and individuals whose efforts contribute to our success. The table below sets forth certain information as of our fiscal year ended December 31, 2003 regarding the shares of our common stock available for grant or granted under the Company's equity compensation plans.

Equity Compensation Plan Information

Plan category	Number of securities to be be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	1,238,825	$ 2.94	1,216,987
Equity compensation plans not approved by security holders (2)	142,556	$ 3.58	0
Total	1,381,381	$ 3.00	1,216,987

(1) Includes the following plans: 1987 Non-Qualified Stock Option Plan, 1999 Non-Qualified Stock Option Plan, Employee Stock Option Plan, and 1999 Employee Stock Purchase Plan.

(2) Includes the following plans: (i) options to purchase 7,000 shares of common stock granted to a former employee upon hiring him: and (ii) warrants to purchase 135,556 shares of common stock issued to the purchasers of convertible debentures issued in August 2000. A description of each of these plans is as follows:

a) In January 1999, the Company granted non-qualified options to purchase 40,000 shares of common stock to a former officer of the Company at an exercise price of $3.25 per share upon the hiring of such officer. These options expire in January 2009. As of December 31, 2003, options to purchase 7,000 shares of common stock remained outstanding.

b) On August 25, 2000, the Company entered into Securities Purchase Agreements providing for the issuance of $3,250,000 (face value) 3% Senior Subordinated Convertible Debentures due August 25, 2003. As of December 31, 2003, none of the 3% Senior Subordinated Convertible Debentures were outstanding. In connection with this transaction, the Company issued warrants, to purchase up to 135,556 shares of the Company's common stock at an exercise price of $3.60 per share. As of December 31, 2003, warrants to purchase 135,556 shares of common stock remained outstanding. These warrants expire in August 2005.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

In August 2000, the Company issued $3,250,000 of 3% Senior Subordinated Convertible Debentures ("the Debentures") to investors, of which $780,000 were issued to Mr. Richard P. Kiphart and $220,000 were issued to Shoreline Micro-Cap Fund I L.P. In January 2001, Mr. Kiphart and Shoreline Micro-Cap Fund I L.P. exercised their conversion rights associated with these Debentures, thereby receiving 662,685 shares of Common Stock of the Company. In December 2001, the Company sold an additional 600,000 shares of Common Stock of the Company for an aggregate purchase price of $1,500,000 in a private placement to five accredited investors including 430,000 shares which were purchased by Mr. Kiphart. The shares were issued in the first quarter of fiscal 2002. As part of this transaction, Mr. Kiphart and Shoreline Micro-Cap Fund I L.P received warrants to purchase 27,734 and 7,822 additional shares of common stock of the Company at an exercise price of $3.60; these warrants remain outstanding as of December 31, 2003 and expire in August 2005.

In 2001, the Company's Board of Directors authorized loans from the Company to Richard T. Schumacher, the Company's former Chairman and Chief Executive Officer and a current Director of the Company, totaling $450,000. Mr. Schumacher borrowed an additional $75,000 from the Company late in 2001. The one year loan was 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 to Mr. Schumacher 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.

In January 2002, the principal of the loan was repaid in full with a portion of the proceeds of the loans described in the following sentence. The Company's loan was replaced by the Company's limited guaranty and 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. Such collateral includes certain of his real property and all of his Company common stock.

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 Company common stock 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 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. 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 includes certain of Mr. Schumacher's common stockholdings in the Company.

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., effective June 30, 2003. 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. During the period February 13, 2003 to June 30, 2003, Mr. Schumacher received $3,777 of compensation from the Company in his role as a member of the Board of Directors during that time frame.

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 and reimbursement for business related travel expenses, 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.

On October 25, 2002, the Company retained the investment banking firm of William Blair and Company to advise the Company in the evaluation of strategic opportunities aimed at increasing shareholder value and liquidity by increasing the capital needed for growth. Mr. Richard P. Kiphart, an investor who owns or controls approximately 22.60% of the common stock of the Company as of December 31, 2003, is a Principal and Head of the Corporate Finance Department of William Blair and Company. Their engagement remains ongoing at this time.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Independent Auditor Fees

The following is a summary of the fees billed to us by PricewaterhouseCoopers LLP ("PwC") prior to its resignation on August 22, 2003 and fees billed to us by Weinberg & Co. ("Weinberg") since its appointment on November 5, 2003 for professional services rendered for the fiscal years ended December 31, 2003 and December 31, 2002:

Fee Category	Fiscal 2003 Fees		Fiscal 2002 Fees	
	Weinberg	PwC	Weinberg	PwC
Audit Fees	$ 137,500	$ 71,325	$ 0	$ 170,000
Audit-Related Fees	0	20,000	0	0
Tax Fees	0	16,600	0	49,000
All Other Fees	0	3,000	0	0
Total Fees	$ 137,500	$ 110,925	$ 0	$ 219,000

Audit Fees. Consists of aggregate fees billed for professional services rendered for the audit of our consolidated financial statements and review of the interim consolidated financial statements included in quarterly reports and services that are normally provided by PwC and Weinberg in connection with statutory and regulatory filings or engagements. Fiscal year 2003 PwC fees include two quarterly reviews, issuance of a year 2003 consent and a final billing on fiscal year 2002 services provided. Fiscal year 2003 fees from Weinberg are estimates based on the 3rd quarter of 2003 review and the year end audit.

Audit-Related Fees. Consists of aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under "Audit Fees." Fees billed by PricewaterhouseCoopers in 2003 included $20,000 for services requested by the Special Oversight Committee of the Board of Directors.

Tax Fees. Consists of aggregate fees billed for professional services for tax compliance, tax advice and tax planning. These services included assistance regarding federal, state tax compliance and tax audit defense.

All Other Fees. In fiscal 2003, services provided by PwC included communications with the successor auditing firm.

The Audit Committee considers whether the provision of these services is compatible with maintaining the auditor's independence, and has determined such services for fiscal 2003 and 2002 were compatible.

Audit Committee Policy on Pre-Approval of Services of Independent Auditors

The Audit Committee's policy is to pre-approve all audit and permissible non-audit services provided by the independent auditors. These services may include audit services, audit-related services, tax services and other services. Pre-approval is generally provided for up to one year. The Audit Committee may also pre-approve particular services on a case-by-case basis.

PART IV.

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

(a) 1. Index to Financial Statements

(a) 2. Financial Statement Schedule:

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:

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10.6	Underwriters Warrants, each dated November 4, 1996, between the Company and each	B**

	of Oscar Gruss & Son Incorporated and Kaufman Bros., L.P.	
10.7	Loan Agreement dated March 31, 2000	C**
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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
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* 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: March 26, 2004

Boston Biomedica, Inc.

By: */s/ Kevin W. Quinlan*
Kevin W. Quinlan
President and Chief Operating Officer
and Treasurer

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

SIGNATURES	TITLES	DATE
/s/ R. Wayne Fritzsche R. Wayne Fritzsche	Director and Chairman of the Board	March 26, 2004
/s/ Kevin W. Quinlan Kevin W. Quinlan	Director, President Chief Operating Officer and Treasurer (Principal Executive Officer)	March 26, 2004
/s/ Michael N. Avallone Michael N. Avallone	Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2004
/s/ J. Donald Payne J. Donald Payne	Director	March 26, 2004
/s/ Richard T. Schumacher Richard T. Schumacher	Director	March 26, 2004
/s/ Calvin A. Saravis, Ph.D. Calvin A. Saravis, Ph. D.	Director	March 26, 2004
/s/ P. Thomas Vogel P. Thomas Vogel	Director	March 26, 2004

SCHEDULE II

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

VALUATION AND QUALIFYING ACCOUNTS

Allowance for Doubtful Accounts	Balance at Beginning of Period	Additions	Recoveries	Deductions	Balance at End of Period
2003	$ 117,671	$ 8,000	$ —	$ (1,388)	$ 124,283
2002	$ 125,617	$ 177	$ —	$ (8,123)	$ 117,671
2001	$ 88,981	$ 55,808	$ 11,310	$ (30,482)	$ 125,617
Inventory Reserve					
2003	$ 886,766	$ 78,000	$ —	$ (114,489)	$ 850,277
2002	$ 796,064	$ 106,372	$ —	$ (15,670)	$ 886,766
2001	$ 765,700	$ 64,891	$ —	$ (34,527)	$ 796,064

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REVOLVING CREDIT AND SECURITY AGREEMENT

THIS REVOLVING CREDIT AND SECURITY AGREEMENT (the **"Agreement"**) dated as of February 5, 2004, is entered into by and among **BOSTON BIOMEDICA, INC**., a Massachusetts corporation ("**Biomedica**"), **BBI BIOTECH RESEARCH LABORATORIES, INC.** a Massachusetts corporation ("**Biotech**"), **BBI SOURCE SCIENTIFIC, INC.** a Massachusetts corporation ("**Source**"), and **BBI BIOSEQ, INC.** a Massachusetts corporation ("**Bioseq**"; individually and collectively, the **"Borrower"**), and **CAPITALSOURCE FINANCE LLC**, a Delaware limited liability company (the **"Lender"**).

WHEREAS, Borrower has requested that Lender make available to Borrower a revolving credit facility (the **"Revolving Facility"**) in a maximum principal amount at any time outstanding of up to Two Million Five Hundred Thousand Dollars ($2,500,000) (the **"Facility Cap"**), the proceeds of which shall be used by Borrower to finance leasehold improvements at its Frederick and Gaithersburg, Maryland facilities, lab improvements for its West Bridgewater, Massachusetts location and for its working capital needs; and

WHEREAS, Lender is willing to make the Revolving Facility available to Borrower upon the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and adequacy of which hereby are acknowledged, Borrower and Lender hereby agree as follows:

I. DEFINITIONS

1.1 General Terms

For purposes of this Agreement, in addition to the definitions above and elsewhere in this Agreement, the terms listed in Appendix A hereto shall have the meanings given such terms in Appendix A, which is incorporated herein and made a part hereof. All capitalized terms used which are not specifically defined shall have meanings provided in Article 9 of the UCC in effect on the date hereof to the extent the same are used or defined therein. Unless otherwise specified herein or in Appendix A, any agreement or contract referred to herein or in Appendix A shall mean such agreement as modified, amended or supplemented from time to time. Unless otherwise specified, as used in the Loan Documents or in any certificate, report, instrument or other document made or delivered pursuant to any of the Loan Documents, all accounting terms not defined in Appendix A or elsewhere in this Agreement shall have the meanings given to such terms in and shall be interpreted in accordance with GAAP.

II. ADVANCES, PAYMENT AND INTEREST

2.1 The Revolving Facility

(a) Subject to the provisions of this Agreement, Lender shall make Advances to Borrower under the Revolving Facility from time to time during the Term, provided that, notwithstanding any other provision of this Agreement, the aggregate amount of all Advances at any one time outstanding under the Revolving Facility shall not exceed either of (a)

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the Facility Cap, and (b) the Availability. The Revolving Facility is a revolving credit facility, which may be drawn, repaid and redrawn, from time to time as permitted under this Agreement. Any determination as to whether there is Availability for Advances shall be made by Lender in its Permitted Discretion and is final and binding upon Borrower. Unless otherwise permitted by Lender, each Advance shall be in an amount of at least $1,000. Subject to the provisions of this Agreement, Borrower may request Advances under the Revolving Facility up to and including the value, in U.S. Dollars, of Eighty-Five percent (85%) of the Borrowing Base minus, if applicable, amounts reserved pursuant to this Agreement (such calculated amount being referred to herein as the **"Availability"**). Advances under the Revolving Facility automatically shall be made for the payment of interest on the Note and other Obligations on the date when due to the extent available and as provided for herein.

(b) Lender has established the above-referenced advance rate for Availability and, in its sole credit judgment, may further adjust the Availability and such advance rate by applying percentages (known as "liquidity factors") to Eligible Receivables by payor class based upon Borrower's actual recent collection history for each such payor class (i.e., commercial contracts, government agency, etc.) in a manner consistent with Lender's underwriting practices and procedures, including without limitation Lender's review and analysis of, among other things, Borrower's historical returns, rebates, discounts, credits and allowances (collectively, the **"Dilution Items"**). Such liquidity factors and the advance rate for Availability may be adjusted by Lender throughout the Term as warranted by Lender's underwriting practices and procedures in its sole credit judgment. Also, Lender shall have the right to establish from time to time, in its sole credit judgment, reserves against the Borrowing Base, which reserves shall have the effect of reducing the amounts otherwise eligible to be disbursed to Borrower under the Revolving Facility pursuant to this Agreement. As of the Closing Date, Lender's review has determined the liquidity factors to be the following: Biomedica - 95%, Biotech - - 100%, and Source - 96%.

2.2 The Note; Maturity

(a) All Advances under the Revolving Facility shall be evidenced by the Note, payable to the order of Lender, duly executed and delivered by Borrower and dated the Closing Date, evidencing the aggregate indebtedness of Borrower to Lender resulting from Advances under the Revolving Facility, from time to time. Lender hereby is authorized, but is not obligated, to enter the amount of

each Advance under the Revolving Facility and the amount of each payment or prepayment of principal or interest thereon in the appropriate spaces on the reverse of or on an attachment to the Note. Lender will account to Borrower monthly with a statement of Advances under the Revolving Facility and charges and payments made pursuant to this Agreement, and in the absence of manifest error, such accounting rendered by Lender shall be deemed final, binding and conclusive unless Lender is notified by Borrower in writing to the contrary within 15 calendar days of Receipt of each accounting, which notice shall be deemed an objection only to items specifically objected to therein.

(b) All amounts outstanding under the Note and other Obligations shall be due and payable in full, if not earlier in accordance with this Agreement, on the earlier of (i) the occurrence of an Event of Default if required pursuant hereto or Lender's demand upon an Event of Default, and (ii) the last day of the Term (such earlier date being the **"Revolving Facility Maturity Date"**).

2.3 Interest

Interest on outstanding Advances under the Note shall be payable monthly in arrears on the first day of each calendar month at an annual rate of Prime Rate plus 3.00%,

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provided, however, that, notwithstanding any provision of any Loan Document, the Prime Rate shall be not less than 4.00%, in each case calculated on the basis of a 360-day year and for the actual number of calendar days elapsed in each interest calculation period. Interest accrued on each Advance under the Note shall be due and payable on the first day of each calendar month, in accordance with the procedures provided for in Section 2.5 and Section 2.6, commencing March 1, 2004, and continuing until the later of the expiration of the Term and the full performance and irrevocable payment in full in cash of the Obligations and termination of this Agreement.

2.4 Revolving Facility Disbursements; Requirement to Deliver Borrowing Certificate

(a) So long as no Default or Event of Default shall have occurred and be continuing, Borrower may give Lender irrevocable written notice requesting an Advance under the Revolving Facility by delivering to Lender not later than 4:00 p.m. (Eastern Standard Time) at least two (2) but not more than four (4) Business Days before the proposed borrowing date of such requested Advance (the **"Borrowing Date"**), a completed Borrowing Certificate and relevant supporting documentation listed on Schedule 2.4 in a form reasonably satisfactory to Lender, which shall (i) specify the proposed Borrowing Date of such Advance which shall be a Business Day, (ii) specify the principal amount of such requested Advance, and (iii) certify the matters contained in Section 4.2.

(b) Each time a request for an Advance is made, and, in any event and regardless of whether an Advance is being requested, on the first and third Tuesday of each month during the Term (and more frequently if Lender shall so request) until the Obligations are indefeasibly paid in cash in full and this Agreement is terminated, Borrower shall deliver to Lender a Borrowing Certificate accompanied by a separate detailed aging and categorizing of Borrower's accounts receivable and accounts payable and such other supporting documentation with respect to the figures and information in the Borrowing Certificate as Lender shall reasonably request from a credit or security perspective or otherwise.

(c) On each Borrowing Date, Borrower irrevocably authorizes Lender to disburse the proceeds of the requested Advance to the appropriate Borrower's account(s) as set forth on Schedule 2.4, in all cases for credit to the appropriate Borrower (or to such other account as to which the appropriate Borrower shall instruct Lender) via Federal funds wire transfer no later than 4:00 p.m. (Eastern Standard Time).

2.5 Revolving Facility Collections; Repayment; Borrowing Availability and Lockbox

Each Borrower shall maintain one or more lockbox accounts (individually and collectively, the **"Lockbox Account"**) with one or more banks acceptable to Lender (each, a **"Lockbox Bank"**), and shall execute with each Lockbox Bank one or more agreements acceptable to Lender (individually and collectively, the **"Lockbox Agreement"**), and such other agreements related thereto as Lender may require. Lender hereby acknowledges that Fleet Bank is an acceptable Lockbox Bank as of the Closing Date. Each Borrower shall ensure that all collections of their respective Accounts are paid and delivered from Account Debtors and other Persons into the appropriate Lockbox Account. The Lockbox Agreements shall provide that the Lockbox Banks immediately will transfer all funds paid into the Lockbox Accounts into a depository account or accounts maintained by Lender or an Affiliate of Lender at such bank as Lender may communicate to Borrower from time to time (the **"Concentration Account"**). Notwithstanding and without limiting any other provision of any Loan Document, Lender shall apply, on a daily basis, all funds transferred into the Concentration Account pursuant to the Lockbox Agreement and this Section 2.5 in such order and manner as determined by Lender

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provided that such amounts shall first be applied to pay any amounts then due. To the extent that any Accounts are collected by any Borrower or any other cash payments received by any Borrower are not sent directly to the appropriate Lockbox Account but are received by any Borrower or any of their Affiliates, such collections and proceeds shall be held in trust for the benefit of Lender and immediately remitted (and in any event within two (2) Business Days), in the form received, to the appropriate Lockbox Account for immediate transfer to the Concentration Account. Borrower acknowledges and agrees that compliance with the terms of this Section 2.5 is an essential term of this Agreement. All funds transferred to the Concentration Account for application to the Obligations under the Revolving Facility shall be applied to reduce the Obligations under the Revolving Facility, but, for purposes of calculating interest hereunder, shall be subject to a five Business Day clearance period. If as the result of collections of Accounts and/or any other cash payments received by any Borrower pursuant to this Section 2.5 a credit balance exists with respect to the Concentration Account, such credit balance shall not accrue interest in favor of a Borrower, but shall be promptly transferred to the appropriate Borrower upon such

Borrower's written request. If applicable, at any time prior to the execution of all or any of the Lockbox Agreements and operation of all or any of the Lockbox Accounts, each Borrower and their Affiliates shall direct all collections or proceeds it receives on Accounts or from other Collateral to the accounts(s) and in the manner specified by Lender in its Permitted Discretion.

2.6 Promise to Pay; Manner of Payment

Borrower absolutely and unconditionally promises to pay principal, interest and all other amounts payable hereunder, or under any other Loan Document, without any right of rescission and without any deduction whatsoever, including any deduction for any setoff, counterclaim or recoupment, and notwithstanding any damage to, defects in or destruction of the Collateral or any other event, including obsolescence of any property or improvements. All payments made by Borrower (other than payments automatically paid through Advances under the Revolving Facility as provided herein), shall be made only by wire transfer on the date when due, without offset or counterclaim, in U.S. Dollars, in immediately available funds to such account as may be indicated in writing by Lender to Borrower from time to time. Any such payment received after 5:00 p.m. (Eastern Standard Time) on the date when due shall be deemed received on the following Business Day. Whenever any payment hereunder shall be stated to be due or shall become due and payable on a day other than a Business Day, the due date thereof shall be extended to, and such payment shall be made on, the next succeeding Business Day, and such extension of time in such case shall be included in the computation of payment of any interest (at the interest rate then in effect during such extension) and/or fees, as the case may be.

2.7 Repayment of Excess Advances

Any balance of Advances under the Revolving Facility outstanding at any time in excess of the lesser of the Facility Cap or the Availability shall be immediately due and payable by Borrower without the necessity of any demand, at the Payment Office, whether or not a Default or Event of Default has occurred or is continuing and shall be paid in the manner specified in Section 2.6.

2.8 Payments by Lender

Should any amount required to be paid under any Loan Document be unpaid on the date due, such amount may be paid by Lender, which payment shall be deemed a request for an Advance under the Revolving Facility as of the date such payment is due, and Borrower irrevocably authorizes disbursement of any such funds to Lender by way of direct payment of the

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relevant amount, interest or Obligations. No payment or prepayment of any amount by Lender or any other Person shall entitle any Person to be subrogated to the rights of Lender under any Loan Document unless and until the Obligations have been fully performed and paid irrevocably in cash and this Agreement has been terminated. Any sums actually expended by Lender as a result of any Borrower's or any Guarantor's failure to pay, perform or comply with any Loan Document or any of the Obligations may be charged to Borrower's account as an Advance under the Revolving Facility and added to the Obligations.

2.9 Grant of Security Interest; Collateral

(a) To secure the payment and performance of the Obligations, each Borrower hereby grants to Lender a continuing security interest in and Lien upon, and pledges to Lender, all of its right, title and interest in and to the following (collectively and each individually, the "**Collateral**"), which security interest is intended to be a first priority security interest:

(i) all of such Borrower's present and future Inventory, now owned or hereafter acquired;

(ii) all of such Borrower's present and future Accounts and all of the following solely to the extent related to such Accounts: contract rights, Permits, General Intangibles, Chattel Paper, Documents, Instruments, Deposit Accounts (which shall include the Lockbox Accounts), Letter-of-Credit Rights, Supporting Obligations, rights to the payment of money or other forms of consideration of any kind, now owned or hereafter acquired;

(iii) all of such Borrower's present and future Government Contracts and rights thereunder and the related Government Accounts and proceeds thereof, now or hereafter owned or acquired by such Borrower; provided, however, that Lender shall not have a security interest in any rights under any Government Contract of such Borrower or in the related Government Account where the taking of such security interest would be a violation of an express prohibition contained in the Government Contract (for purposes of this limitation, the fact that a Government Contract is subject to, or otherwise refers to, Title 31, § 203 or Title 41, § 15 of the United States Code shall not be deemed an express prohibition against assignment thereof) or is prohibited by applicable law;

(iv) All Books and Records, whether now owed or hereafter acquired; and

(v) any and all additions and accessions to any of the foregoing, and any and all replacements, products and Proceeds (including insurance proceeds) of any of the foregoing.

(b) Notwithstanding the foregoing provisions of this Section 2.9, such grant of a security interest shall not extend to, and the term "Collateral" shall not include, any General Intangibles of Borrower to the extent that (i) such General Intangible does not directly relate to the Accounts; or (ii) (A) such General Intangibles are not assignable or capable of being encumbered as a matter of law or under the terms of any license or other agreement applicable thereto (but solely to the extent that any such restriction shall be enforceable under applicable law) without the consent of the licensor thereof or other applicable party thereto, and (B) such consent has not been obtained; provided, however, that the foregoing grant of a security interest shall extend to, and the term "Collateral" shall include, each of the following: (a) any General

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Intangible directly related to the Accounts which is in the nature of an Account or a right to the payment of money or a proceed of, or otherwise related to the enforcement or collection of, any Account or right to the payment of money, or goods which are the subject of any Account or right to the payment of money, (b) any and all proceeds of any General Intangible which related to the Accounts that is otherwise excluded pursuant to subsection (i) to the extent that the assignment, pledge or encumbrance of such proceeds is not so restricted, and (c) upon obtaining the consent of any such licensor or other applicable party with respect to any such otherwise excluded General Intangible, such General Intangible as well as any and all proceeds thereof that might theretofore have been excluded from such grant of a security interest and from the term "Collateral."

(d) Upon the execution and delivery of this Agreement, and upon the proper filing of the necessary financing statements, without any further action, Lender will have a good, valid and perfected first priority Lien and security interest in the Collateral, subject to no transfer or other restrictions or Liens of any kind in favor of any other Person except for Permitted Liens. No financing statement relating to any of the Collateral is on file in any public office except those (i) on behalf of Lender, and/or (ii) in connection with Permitted Liens.

2.10 Collateral Administration

(a) All Collateral (except Deposit Accounts) will at all times be kept by Borrower at the locations set forth on Schedule 5.18B hereto and shall not, without thirty (30) calendar days prior written notice to Lender, be moved therefrom, and in any case shall not be moved outside the continental United States.

(b) Borrower shall keep accurate and complete records of its Accounts and all payments and collections thereon and shall submit such records to Lender on such periodic bases as Lender may reasonably request. In addition, if Accounts of Borrower in an aggregate face amount in excess of $10,000 become ineligible because they fall within one of the specified categories of ineligibility set forth in the definition of Eligible Receivables, Borrower shall notify Lender of such occurrence on the first Business Day following such occurrence and the Borrowing Base shall thereupon be adjusted to reflect such occurrence. If requested by Lender, Borrower shall execute and deliver to Lender formal written assignments of all of its Accounts weekly or daily as Lender may reasonably request, including all Accounts created since the date of the last assignment, together with copies of claims, invoices and/or other information related thereto. To the extent that collections from such assigned accounts exceed the amount of the Obligations, such excess amount shall not accrue interest in favor of Borrower, but shall be available to Borrower upon Borrower's written request.

(c) Whether or not an Event of Default has occurred, any of Lender's officers, employees, representatives or agents shall have the right, at any time during normal business hours, in the name of Lender, any designee of Lender or Borrower, to verify the validity, amount or any other matter relating to any Accounts of Borrower. Borrower shall cooperate fully with Lender in an effort to facilitate and promptly conclude such verification process.

(d) To expedite collection, Borrower shall endeavor in the first instance to make collection of its Accounts for Lender. Lender shall have the right at all times after the occurrence and during the continuance of an Event of Default to notify Account Debtors owing Accounts to Borrower that their Accounts have been assigned to Lender and to collect such

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Accounts directly in its own name and to charge collection costs and expenses, including reasonable attorney's fees, to Borrower.

(e) As and when determined by Lender in its Permitted Discretion, Lender will perform the searches described in clauses (i) and (ii) below against Borrower and Guarantors (the results of which are to be consistent with Borrower's representations and warranties under this Agreement), all at Borrower's expense: (i) UCC searches with the Secretary of State of the jurisdiction of organization of each Borrower and Guarantor and the Secretary of State and local filing offices of each jurisdiction where Borrower and/or any Guarantors maintain their respective executive offices, a place of business or assets; and (ii) judgment, federal tax lien and corporate and partnership tax lien searches, in each jurisdiction searched under clause (i) above.

(f) Borrower (i) shall provide prompt written notice to its current bank to transfer all items, collections and remittances to the Concentration Account, (ii) shall direct each Account Debtor to make payments to the appropriate Lockbox Account, and Borrower hereby authorizes Lender, upon any failure to send such notices and directions within ten (10) calendar days after the date of this Agreement (or ten (10) calendar days after the Person becomes an Account Debtor), to send any and all similar notices and directions to such Account Debtors, and (iii) shall do anything further that may be lawfully required by Lender to create and perfect Lender's lien on any collateral and effectuate the intentions of the Loan Documents. At Lender's request, Borrower shall immediately deliver to Lender all items for which Lender must receive possession to obtain a perfected security interest and all notes, certificates, and documents of title, Chattel Paper, warehouse receipts, Instruments, and any other similar instruments constituting Collateral.

2.11 Power of Attorney

Lender is hereby irrevocably made, constituted and appointed the true and lawful attorney for Borrower (without requiring any of them to act as such) with full power of substitution to do the following: (i) endorse the name of Borrower upon any and all checks, drafts, money orders, and other instruments for the payment of money that are payable to Borrower and constitute collections on its or their Accounts; (ii) execute in the name of Borrower any financing statements, schedules, assignments, instruments, documents, and statements that it is or they or are obligated to give Lender under any of the Loan Documents; and (iii) do such other and further acts and deeds in the name of Borrower that Lender may reasonably deem necessary or desirable to enforce any Account or other Collateral or to perfect Lender's security interest or lien in any Collateral. In addition, if any Borrower breaches its obligation hereunder to direct payments of Accounts or the proceeds of any other Collateral to the appropriate Lockbox Account, Lender, as the irrevocably made, constituted and appointed true and lawful attorney for Borrower pursuant to this paragraph, may, by the signature or other act of any of

Lender's officers or authorized signatories (without requiring any of them to do so), direct any federal, state or private payor or fiscal intermediary to pay proceeds of Accounts or any other Collateral to the appropriate Lockbox Account.

III. FEES AND OTHER CHARGES

3.1 Commitment Fee

On or before the Closing Date, Borrower shall pay to Lender 1% of the Facility Cap as a nonrefundable commitment fee.

3.2 Unused Line Fee

Borrower shall pay to Lender monthly an unused line fee (the **"Unused Line Fee"**) in an amount equal to 0.042% (per month) of the difference derived by subtracting (i) the daily average amount of the balances under the Revolving Facility outstanding during the preceding month, from (ii) the Facility Cap. The Unused Line Fee shall be payable monthly in arrears on the first day of each successive calendar month (starting with the month in which the Closing Date occurs).

3.3 Collateral Management Fee

Borrower shall pay Lender as additional interest a monthly collateral management fee (the **"Collateral Management Fee"**) equal to 0.083% per month calculated on the basis of the daily average amount of the balances under the Revolving Facility outstanding during the preceding month. The Collateral Management Fee shall be payable monthly in arrears on the first day of each successive calendar month (starting with the month in which the Closing Date occurs).

3.4 Computation of Fees; Lawful Limits

All fees hereunder shall be computed on the basis of a year of 360 days and for the actual number of days elapsed in each calculation period, as applicable. In no contingency or event whatsoever, whether by reason of acceleration or otherwise, shall the interest and other charges paid or agreed to be paid to Lender for the use, forbearance or detention of money hereunder exceed the maximum rate permissible under applicable law which a court of competent jurisdiction shall, in a final determination, deem applicable hereto. If, due to any circumstance whatsoever, fulfillment of any provision hereof, at the time performance of such provision shall be due, shall exceed any such limit, then, the obligation to be so fulfilled shall be reduced to such lawful limit, and, if Lender shall have received interest or any other charges of any kind which might be deemed to be interest under applicable law in excess of the maximum lawful rate, then such excess shall be applied first to any unpaid fees and charges hereunder, then to unpaid principal balance owed by Borrower hereunder, and if the then remaining excess interest is greater than the previously unpaid principal balance, Lender shall promptly refund such excess amount to Borrower and the provisions hereof shall be deemed amended to provide for such permissible rate. The terms and provisions of this Section 3.4 shall control to the extent any other provision of any Loan Document is inconsistent herewith.

3.5 Default Rate of Interest

Upon the occurrence and during the continuation of an Event of Default, the Applicable Rate of interest in effect at such time with respect to the Obligations shall be increased by 3.0% per annum (the **"Default Rate"**).

3.6 Acknowledgement of Joint and Several Liability

Each Borrower acknowledges that it is jointly and severally liable for all of the Obligations under the Loan Documents. Each Borrower expressly understands, agrees and acknowledges that (i) Borrowers are all Affiliated entities by common ownership, (ii) each Borrower desires to have the availability of one common credit facility instead of separate credit facilities, (iii) each Borrower has requested that Lender extend such a common credit facility on the terms herein provided, (iv) Lender will be lending against, and relying on a lien upon, all of Borrowers' Collateral even though the proceeds of any particular loan made hereunder may not be advanced directly to a particular Borrower, (v) each Borrower will nonetheless benefit by the

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making of all such loans by Lender and the availability of a single credit facility of a size greater than each could independently warrant, and (vi) all of the representations, warranties, covenants, obligations, conditions, agreements and other terms contained in the Loan Documents shall be applicable to and shall be binding upon each Borrower.

IV. CONDITIONS PRECEDENT

4.1 Conditions to Initial Advance and Closing

The obligations of Lender to consummate the transactions contemplated herein and to make the initial Advance under the Revolving Facility (the **"Initial Advance"**) are subject to the satisfaction, in the reasonable judgment of Lender, of the following:

(a) (i) Borrower shall have delivered to Lender (A) the Loan Documents to which it is a party, each duly executed by an authorized officer of Borrower and the other parties thereto, (B) a Borrowing Certificate for the Initial Advance under the Revolving Facility executed by an authorized officer of Borrower;

(b) all in form and substance satisfactory to Lender in its Permitted Discretion, Lender shall have received (i) a report of Uniform Commercial Code financing statement, tax and judgment lien searches performed with respect to each Borrower in each jurisdiction determined by Lender in its Permitted Discretion, and such report shall show no Liens on the Collateral (other than Permitted Liens), (ii) each document (including, without limitation, any Uniform Commercial Code financing statement) required by any Loan Document or under law or requested by Lender to be filed, registered or recorded to create in favor of Lender, a perfected first priority security interest upon the Collateral, and (iii) evidence of each such filing, registration or recordation and of the payment by Borrower of any necessary fee, tax or expense relating thereto;

(c) Lender shall have received (i) the Charter and Good Standing Documents, all in form and substance acceptable to Lender, (ii) a certificate of the corporate secretary or assistant secretary of each Borrower dated the Closing Date, as to the incumbency and signature of the Persons executing the Loan Documents, in form and substance acceptable to Lender, and (iii) the written legal opinion of counsel for Borrower, in form and substance satisfactory to Lender and its counsel;

(d) Lender shall have received a certificate of the chief financial officer (or, in the absence of a chief financial officer, the chief executive officer) of each Borrower, in form and substance satisfactory to Lender (each, a **"Solvency Certificate"**), certifying as to such Person's financial resources and ability to meet its obligations and liabilities as they become due, to the effect that as of the Closing Date and the Borrowing Date for the Initial Advance and after giving effect to such transactions and Indebtedness: (A) the assets of such Person, at a Fair Valuation, exceed the total liabilities (including contingent, subordinated, unmatured and unliquidated liabilities) of such Person, and (B) no unreasonably small capital base with which to engage in its anticipated business exists with respect to such Person;

(e) Lender shall have completed examinations, the results of which shall be satisfactory in form and substance to Lender, of the Collateral, the financial statements and the books, records, business, obligations, financial condition and operational state of each Borrower, and each such Person shall have demonstrated to Lender's satisfaction that (i) its operations comply, in all respects deemed material by Lender, in its reasonable judgment, with all applicable

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federal, state, foreign and local laws, statutes and regulations, (ii) its operations are not the subject of any governmental investigation, evaluation or any remedial action which could result in any expenditure or liability deemed material by Lender, in its reasonable judgment, and (iii) it has no liability (whether contingent or otherwise) that is deemed material by Lender, in its reasonable judgment;

(f) Lender shall have received all fees, charges and expenses payable to Lender on or prior to the Closing Date pursuant to the Loan Documents;

(g) all in form and substance satisfactory to Lender in its Permitted Discretion, Lender shall have received such consents, approvals and agreements, including, without limitation, any applicable Landlord Waivers and Consents with respect to any and all leases set forth on Schedule 5.4, from such third parties as Lender and its counsel shall determine are necessary or desirable with respect to (i) the Loan Documents and/or the transactions contemplated thereby, and/or (ii) claims against any Borrower or the Collateral;

(h) Borrower shall be in compliance with Section 6.5, and Lender shall have received original certificates of all insurance policies of Borrower confirming that they are in effect and that the premiums due and owing with respect thereto have been paid in full and naming Lender as an additional insured, as such insurance relates to the Collateral;

(i) all corporate and other proceedings, documents, instruments and other legal matters in connection with the transactions contemplated by the Loan Documents (including, but not limited to, those relating to corporate and capital structures of Borrower) shall be satisfactory to Lender;

(j) Lender shall have received, in form and substance satisfactory to Lender, release and termination of any and all Liens, security interest and/or Uniform Commercial Code financing statements in, on, against or with respect to any of the Collateral (other than Permitted Liens);

(k) Borrower shall have executed and filed IRS Form 8821 with the appropriate office of the Internal Revenue Service;

(l) Borrower shall provide evidence that it has engaged a nationally recognized independent certified public accounting firm satisfactory to Lender in its Permitted Discretion; and

(m) Lender shall have received such other documents, certificates, information or legal opinions as Lender may reasonably request, all in form and substance reasonably satisfactory to Lender.

4.2 Conditions to Each Advance

The obligations of Lender to make any Advance (including, without limitation, the Initial Advance) are subject to the satisfaction, in the reasonable judgment of Lender, of the following additional conditions precedent:

(a) Borrower shall have delivered to Lender a Borrowing Certificate for the Advance executed by an authorized officer of Borrower, which shall constitute a representation

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and warranty by Borrower as of the Borrowing Date of such Advance that the conditions contained in this Section 4.2 have been satisfied;

(b) each of the representations and warranties made by Borrower in or pursuant to this Agreement (as updated from time to time by Borrower) shall be accurate, before and after giving effect to such Advance, and no Default or Event of Default shall have occurred or be continuing or would exist after giving effect to the Advance under the Revolving Facility on such date;

(c) immediately after giving effect to the requested Advance, the aggregate outstanding principal amount of Advances under the Revolving Facility shall not exceed either the Availability or the Facility Cap;

(d) except as disclosed in the financial statements provided to the Lender prior to the date of the requested Advance, there shall be no liabilities or obligations with respect to Borrower of any nature whatsoever which, either individually or in the aggregate, would reasonably be likely to have a Material Adverse Effect; and

(e) Lender shall have received all fees, charges and expenses payable to Lender on or prior to such date pursuant to the Loan Documents.

V. REPRESENTATIONS AND WARRANTIES

Each Borrower, jointly and severally, represents and warrants as of the date hereof, the Closing Date, and each Borrowing Date as follows:

5.1 Organization and Authority

Borrower is a corporationduly organized, validly existing and in good standing under the laws of its state of formation. Borrower (i) has all requisite corporate power and authority to own its properties and assets and to carry on its business as now being conducted and as contemplated in the Loan Documents, (ii) is duly qualified to do business in every jurisdiction in which failure so to qualify would reasonably be likely to have a Material Adverse Effect, and (iii) has all requisite power and authority (A) to execute, deliver and perform the Loan Documents to which it is a party, (B) to borrow hereunder, (C) to consummate the transactions contemplated under the Loan Documents, and (D) to grant the Liens with regard to the Collateral pursuant to the Security Documents to which it is a party. No Borrower is an "investment company" registered or required to be registered under the Investment Company Act of 1940, as amended, or is controlled by such an "investment company."

5.2 Loan Documents

The execution, delivery and performance by Borrower of the Loan Documents to which it is a party, and the consummation of the transactions contemplated thereby, (i) have been duly authorized by all requisite action of each such Person and have been duly executed and delivered by or on behalf of each such Person; (ii) do not violate any provisions of (A) applicable law, statute, rule, regulation, ordinance or tariff, (B) any order of any Governmental Authority binding on any such Person or any of their respective properties, or (C) the certificate of incorporation or bylaws (or any other equivalent governing agreement or document) of any such Person, or any agreement between any such Person and its respective stockholders, members, partners or equity owners or among any such stockholders, members, partners or equity owners; (iii) are not in conflict with, and do not result in a breach or default of or constitute an event of

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default, or an event, fact, condition or circumstance which, with notice or passage of time, or both, would constitute or result in a conflict, breach, default or event of default under, any indenture, agreement or other instrument to which any such Person is a party, or by which the properties or assets of such Person are bound; (iv) except as set forth therein, will not result in the creation or imposition of any Lien of any nature upon any of the properties or assets of any such Person, and (v) except as set forth on Schedule 5.2, do not require the consent, approval or authorization of, or filing, registration or qualification with, any Governmental Authority or any other Person. When executed and delivered, each of the Loan Documents to which Borrower is a party will constitute the legal, valid and binding obligation of Borrower, enforceable against Borrower in accordance with its terms, subject to the effect of any applicable bankruptcy, moratorium, insolvency, reorganization or other similar law affecting the enforceability of creditors' rights generally and to the effect of general principles of equity which may limit the availability of equitable remedies (whether in a proceeding at law or in equity).

5.3 Subsidiaries, Capitalization and Ownership Interests

Except as listed on Schedule 5.3, Borrower has no Subsidiaries. Schedule 5.3 states the authorized and issued capitalization of Borrower, the number and class of equity securities and/or ownership, voting or partnership interests issued and outstanding of Borrower and the record and beneficial owners thereof (including options, warrants and other rights to acquire any of the foregoing). The outstanding equity securities and/or ownership, voting or partnership interests of Borrower have been duly authorized and validly issued and are fully paid and nonassessable, and each Person listed on Schedule 5.3 owns beneficially and of record all the equity securities and/or ownership, voting or partnership interests it is listed as owning free and clear of any Liens other than Liens created by the Security Documents. Schedule 5.3 also lists the directors, members, managers and/or partners of Borrower. Except as listed on Schedule 5.3, Borrower does not own an interest in, participate in or engage in any joint venture, partnership or similar arrangements with any Person.

5.4 Properties

Borrower (i) (A) is the sole owner and has good, valid and marketable title to, or (B) has a valid leasehold interest in or license to, all of its properties and assets, including the Collateral, whether personal or real, subject to no transfer restrictions or Liens of

any kind except for Permitted Liens, and (ii) is in compliance in all material respects with each material lease to which it is a party or otherwise bound. Schedule 5.4 lists all real properties (and their locations) owned or leased by or to, and all other assets or property with a value in excess of $50,000 that are leased or licensed by, Borrower and all leases (including leases of leased real property) covering or with respect to such properties and assets. Borrower enjoys peaceful and undisturbed possession under all such leases and such leases are all the leases necessary for the operation of such properties and assets, are valid and subsisting and are in full force and effect.

5.5 Other Agreements

Borrower is not (i) a party to any judgment, order or decree or any agreement, document or instrument, or subject to any restriction, which would materially adversely affect its ability to execute and deliver, or perform under, any Loan Document or to pay the Obligations, (ii) in default in the performance, observance or fulfillment of any obligation, covenant or condition contained in any agreement, document or instrument to which it is a party or to which any of its properties or assets are subject, which default, if not remedied within any applicable grace or cure period would reasonably be likely to have a Material Adverse Effect, nor is there

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any event, fact, condition or circumstance which, with notice or passage of time or both, would constitute or result in a conflict, breach, default or event of default under, any of the foregoing which, if not remedied within any applicable grace or cure period would reasonably be likely to have a Material Adverse Effect; or (iii) a party or subject to any agreement, document or instrument with respect to, or obligation to pay any, service fee or management fee with respect to, the ownership, operation, leasing or performance of any of its business or any facility, nor is there any manager with respect to any such facility.

5.6 Litigation

There is no action, suit, proceeding or investigation pending or, to their knowledge, threatened against Borrower that (i) questions or could prevent the validity of any of the Loan Documents or the right of Borrower to enter into any Loan Document or to consummate the transactions contemplated thereby, (ii) would reasonably be likely to be or have, either individually or in the aggregate, any Material Adverse Change or Material Adverse Effect, or (iii) would reasonably be likely to result in any Change of Control or other change in the current ownership, control or management of Borrower. Borrower is not aware that there is any basis for the foregoing. Borrower is not a party or subject to any order, writ, injunction, judgment or decree of any Governmental Authority. There is no action, suit, proceeding or investigation initiated by Borrower currently pending. Borrower has no existing accrued and/or unpaid Indebtedness to any Governmental Authority or any other governmental payor.

5.7 Hazardous Materials

Borrower is in compliance in all material respects with all applicable Environmental Laws. Borrower has not been notified of any action, suit, proceeding or investigation (i) relating in any way to compliance by or liability of Borrower under any Environmental Laws, (ii) which otherwise deals with any Hazardous Substance or any Environmental Law, or (iii) which seeks to suspend, revoke or terminate any license, permit or approval necessary for the generation, handling, storage, treatment or disposal of any Hazardous Substance.

5.8 Potential Tax Liability; Tax Returns; Governmental Reports

(a) Except as disclosed in Schedule 5.8, Borrower (i) has not received any oral or written communication from the Internal Revenue Service with respect to any investigation or assessment relating to the Borrower directly, or relating to any consolidated tax return which was filed on behalf of Borrower, (ii) is not aware of any year which remains open pending tax examination or audit by the IRS, and (iii) is not aware of any information that could give rise to an IRS tax liability or assessment.

(b) Borrower (i) has filed all federal, state, foreign (if applicable) and local tax returns and other reports which are required by law to be filed by Borrower, and (ii) has paid all taxes, assessments, fees and other governmental charges, including, without limitation, payroll and other employment related taxes, in each case that are due and payable, except only for items that Borrower is currently contesting in good faith with adequate reserves under GAAP, which contested items are described on Schedule 5.8.

5.9 Financial Statements and Reports

All financial statements and financial information relating to Borrower that have been or may hereafter be delivered to Lender by Borrower are accurate and complete and have been prepared in accordance with GAAP consistently applied with prior periods; provided, however, that such monthly and/or quarterly statements may not contain footnotes and are subject to year-end adjustments. Borrower has no material obligations or liabilities of any kind not disclosed in such financial information or statements, and since the date of the most recent financial statements submitted to Lender, there has not occurred any Material Adverse Change, Material Adverse Effect or, to Borrower's knowledge, any other event or condition that would reasonably be likely to have a Material Adverse Effect.

5.10 Compliance with Law

Borrower (i) is in compliance with all laws, statutes, rules, regulations, ordinances and tariffs of any Governmental Authority applicable to Borrower and/or Borrower's business, assets or operations, including, without limitation, applicable requirements of the Standards for Privacy of Individually Identifiable Health Information which were promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), ERISA and Healthcare Laws, and (ii) is not in violation of any order of any

Governmental Authority or other board or tribunal, except in the case of (i) and (ii) above where noncompliance or violation could not reasonably be expected to have a Material Adverse Effect. There is no event, fact, condition or circumstance which, with notice or passage of time, or both, would constitute or result in any noncompliance with, or any violation of, any of the foregoing, in each case except where noncompliance or violation could not reasonably be expected to have a Material Adverse Effect. Borrower has not received any notice that Borrower is not in compliance in any respect with any of the requirements of any of the foregoing. Borrower has (a) not engaged in any Prohibited Transactions as defined in Section 406 of ERISA and Section 4975 of the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder, (b) not failed to meet any applicable minimum funding requirements under Section 302 of ERISA in respect of its plans and no funding requirements have been postponed or delayed, (c) no knowledge of any event or occurrence which would cause the Pension Benefit Guaranty Corporation to institute proceedings under Title IV of ERISA to terminate any of the employee benefit plans, (d) no fiduciary responsibility under ERISA for investments with respect to any plan existing for the benefit of Persons other than its employees or former employees, or (e) not withdrawn, completely or partially, from any multi-employer pension plans so as to incur liability under the MultiEmployer Pension Plan Amendments of 1980. With respect to Borrower, there exists no event described in Section 4043 of ERISA, excluding Subsections 4043(b)(2) and 4043(b)(3) thereof, for which the thirty (30) day notice period contained in 12 C.F.R. § 2615.3 has not been waived. Borrower has maintained in all material respects all records required to be maintained by the Joint Commission on Accreditation of Healthcare Organizations, the Food and Drug Administration, Drug Enforcement Agency and State Boards of Pharmacy, and, to the best knowledge of Borrower, there are no presently existing circumstances which likely would result in material violations of the Healthcare Laws.

5.11 Intellectual Property

Borrower owns or has the rights to all patents, patent applications, trademarks, trademark applications, service marks, registered copyrights, copyright applications, copyrights, trade names, trade secrets, software or licenses (collectively, the **"Intellectual Property"**) necessary for its business. Each Borrower's patents and registered trademarks are listed on Schedule 5.11.

5.12 Licenses and Permits; Labor

Borrower is in compliance with and has all Permits and rights to Intellectual Property necessary or required by applicable law or Governmental Authority for the operation of its businesses. All of the foregoing are in full force and effect and not in known conflict with the rights of others. Borrower is not (i) in breach of or default under the provisions of any of the foregoing, nor is there any event, fact, condition or circumstance which, with notice or passage of time or both, would constitute or result in a conflict, breach, default or event of default under, any of the foregoing which, if not remedied within any applicable grace or cure period would reasonably be likely to have a Material Adverse Effect or (ii) has not been involved in any labor dispute, strike, walkout or union organization which would reasonably be likely to have a Material Adverse Effect.

5.13 No Default

There does not exist any Default or Event of Default or any event, fact, condition or circumstance which, with the giving of notice or passage of time or both, would constitute or result in a Default or Event of Default.

5.14 Disclosure

No Loan Document nor any other agreement, document, certificate, or statement furnished to Lender by or on behalf of Borrower in connection with the transactions contemplated by the Loan Documents, nor any representation or warranty made by Borrower in any Loan Document, contains any untrue statement of material fact or omits to state any fact necessary to make the statements therein not materially misleading. There is no fact known to Borrower which has not been disclosed to Lender in writing which would reasonably be likely to have a Material Adverse Effect.

5.15 Existing Indebtedness; Investments, Guarantees and Certain Contracts

Except as contemplated by the Loan Documents or as otherwise set forth on Schedule 5.15, Borrower (i) has no outstanding Indebtedness, (ii) is not subject or party to any mortgage, note, indenture, indemnity or guarantee of, with respect to or evidencing any Indebtedness of any other Person, or (iii) does not own or hold any equity or long-term debt investments in, and does not have any outstanding advances to or any outstanding guarantees for the obligations of, or any outstanding borrowings from, any Person. Borrower has performed all material obligations required to be performed by Borrower pursuant to or in connection with any items listed on Schedule 5.15 and there has occurred no breach, default or event of default under any document evidencing any such items or any fact, circumstance, condition or event which, with the giving of notice or passage of time or both, would constitute or result in a breach, default or event of default thereunder.

5.16 Other Agreements

Except as set forth on Schedule 5.16, (i) there are no existing or proposed agreements, arrangements, understandings or transactions between Borrower and any of Borrower's officers, members, managers, directors, stockholders, partners, other interest holders, employees or Affiliates or any members of their respective immediate families, and (ii) none of the foregoing Persons are directly or indirectly, indebted to or have any direct or indirect ownership, partnership or voting interest in, to Borrower's knowledge, any Affiliate of Borrower

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or any Person that competes with Borrower (except that any such Persons may own stock in (but not exceeding two (2%) percent of the

outstanding capital stock of) any publicly traded company that may compete with Borrower.

5.17 Insurance

Borrower has in full force and effect such insurance policies as are customary in its industry and as may be required pursuant to Section 6.5 hereof. All such insurance policies are listed and described on Schedule 5.17.

5.18 Names; Location of Offices, Records and Collateral

During the preceding five years, Borrower has not conducted business under or used any name (whether corporate, partnership or assumed) other than as shown on Schedule 5.18A. Borrower is the sole owner of all of its names listed on Schedule 5.18A, and any and all business done and invoices issued in such names are Borrower's sales, business and invoices. Each trade name of Borrower represents a division or trading style of Borrower. Borrower maintains its places of business and chief executive offices only at the locations set forth on Schedule 5.18B, and all Accounts of Borrower arise, originate and are located, and all of the Collateral and all books and records in connection therewith or in any way relating thereto or evidencing the Collateral are located and shall only be located, in and at such locations. All of the Collateral is located only in the continental United States.

5.19 Non-Subordination

The Obligations are not subordinated in any way to any other obligations of Borrower or to the rights of any other Person.

5.20 Accounts

In determining which Accounts are Eligible Receivables, Lender may rely on all statements and representations made by Borrower with respect to any Account. Unless otherwise indicated in writing to Lender, (i) each Account of Borrower is genuine and in all respects what it purports to be and is not evidenced by a judgment, (ii) each Account of Borrower arises out of a completed, bona fide sale and delivery of goods or rendering of services by Borrower in the ordinary course of business and in accordance with the terms and conditions of all purchase orders, contracts, certifications, participations, certificates of need and other documents relating thereto or forming a part of the contract between Borrower and the Account Debtor, (iii) each Account of Borrower is for a liquidated amount maturing as stated in a claim or invoice covering such sale of goods or rendering of services, a copy of which has been furnished or is available to Lender, (iv) each Account of Borrower together with Lender's security interest therein, is not and will not be in the future (by voluntary act or omission by Borrower), subject to any offset, lien, deduction, defense, dispute, counterclaim or other adverse condition except as reserved against in the financial statements, is absolutely owing to Borrower and is not contingent in any respect or for any reason, (v) except as reserved against in the financial statements, there are no facts, events or occurrences which in any way impair the validity or enforceability of any Account of Borrower or tend to reduce the amount payable thereunder from the face amount of the claim or invoice and statements delivered to Lender with respect thereto, (vi) (A) with respect to contracts or other documents generating more than $1000 in Accounts on an annual basis, (I) the Account Debtor under each such Account of Borrower had the capacity to contract at the time any such contract or other document giving rise thereto was executed and (II) each such Account Debtor

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thereunder is solvent, and (B) with respect to contracts or other documents generating $1000 or less in Accounts on an annual basis, to the best of Borrower's knowledge (I) the Account Debtor under each such Account of Borrower had the capacity to contract at the time any such contract or other document giving rise thereto was executed and (II) each such Account Debtor thereunder is solvent, (vii) there are no proceedings or actions which are threatened or pending against any Account Debtor under any Account of Borrower which might result in any Material Adverse Change in such Account Debtor's financial condition or the collectability thereof, (viii) each Account of Borrower has been billed and forwarded to the Account Debtor for payment in accordance with applicable laws and is in compliance and conformance with any requisite procedures, requirements and regulations governing payment by such Account Debtor with respect to such Account, and (ix) Borrower has obtained and currently has all Permits necessary in the generation of each Account of Borrower.

5.21 Regulatory Requirements

Without limiting or being limited by any other provision of any Loan Document, Borrower has timely filed or caused to be filed all cost and other reports of every kind required by law, agreement or otherwise. There are no claims, actions or appeals pending (and Borrower has not filed any claims or reports which could reasonably result in any such claims, actions or appeals) before any commission, board or agency or other Governmental Authority.

5.22 Survival

Borrower makes the representations and warranties contained herein with the knowledge and intention that Lender is relying and will rely thereon. All such representations and warranties will survive the execution and delivery of this Agreement and the making of the Advances under the Revolving Facility.

VI. AFFIRMATIVE COVENANTS

Each Borrower, jointly and severally, covenants and agrees that, until full performance and satisfaction, and indefeasible payment in full in cash, of all the Obligations and termination of this Agreement:

6.1 Financial Statements, Borrowing Certificate, Financial Reports and Other Information

(a) Financial Reports. In addition to providing the Borrowing Certificate in accordance with Section 2.4,

Borrower shall furnish to Lender (i) as soon as available and in any event within ninety (90) calendar days after the end of each fiscal year of Borrower, audited annual consolidated financial statements of Borrower, including the notes thereto, consisting of a consolidated balance sheet at the end of such completed fiscal year and the related consolidated statement of income, retained earnings, cash flows and owners' equity for such completed fiscal year, which financial statements shall be prepared and certified without qualification by an independent certified public accounting firm reasonably satisfactory to Lender and accompanied by related management letters, if available, and (ii) as soon as available and in any event within forty-five (45) calendar days after the end of each calendar month, unaudited consolidated and consolidating financial statement of Borrower consisting of a balance sheet and statements of income, as of the end of the immediately preceding calendar month, and unaudited statements of retained earnings, cash flows and owners' equity as of the end of each calendar quarter. All such financial statements shall be prepared in accordance with GAAP consistently applied with prior

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periods. With each such financial statement, Borrower shall also deliver a certificate of its chief financial officer stating that (A) such person has reviewed the relevant terms of the Loan Documents and the condition of Borrower, (B) no Default or Event of Default has occurred or is continuing, or, if any of the foregoing has occurred or is continuing, specifying the nature and status and period of existence thereof and the steps taken or proposed to be taken with respect thereto, and (C) Borrower is in compliance with all financial covenants attached as Annex I hereto. Such certificate shall be accompanied by the calculations necessary to show compliance with the financial covenants in a form satisfactory to Lender.

(b) Other Materials. Borrower shall furnish to Lender as soon as available, and in any event within ten (10) calendar days after the preparation or issuance thereof or at such other time as set forth below: (i) any reports, returns, information, notices and other materials that Borrower shall send to its stockholders, members, partners or other equity owners at any time, (ii) within fifteen (15) calendar days after the end of each calendar month for such month, a sales and collection report and accounts receivable and accounts payable aging schedule, including a report of sales, credits issued and collections received, all such reports showing a reconciliation to the amounts reported in the monthly financial statements, (iii) promptly upon receipt thereof, copies of any reports submitted to Borrower by its independent accountants in connection with any interim audit of the books of such Person or any of its Affiliates and copies of each management control letter provided by such independent accountants, and (iv) such additional information, documents, statements, reports and other materials as Lender may reasonably request from a credit or security perspective or otherwise from time to time.

(c) Notices. Borrower shall promptly, and in any event within two (2) calendar days after Borrower or any authorized officer of Borrower obtains knowledge thereof, notify Lender in writing of (i) any pending or threatened litigation, suit, investigation, arbitration, dispute resolution proceeding or administrative proceeding brought or initiated by Borrower or otherwise affecting or involving or relating to Borrower or any of its property or assets to the extent (A) the amount in controversy exceeds $10,000, or (B) to the extent any of the foregoing seeks injunctive or declarative relief, (ii) any Default or Event of Default, which notice shall specify the nature and status thereof, the period of existence thereof and what action is proposed to be taken with respect thereto, (iii) any other development, event, fact, circumstance or condition that would reasonably be likely to have a Material Adverse Effect, in each case describing the nature and status thereof and the action proposed to be taken with respect thereto, (iv) any notice received by Borrower from any payor of a claim, suit or other action such payor has, claims or has filed against Borrower, (v) any matter(s) affecting the value, enforceability or collectability of any of the Collateral, including, without limitation, claims or disputes in the amount of $50,000 or more, singly or in the aggregate, in existence at any one time, (vi) any notice given by Borrower to any other lender of Borrower, which notice to Lender shall be accompanied by a copy of the applicable notice given to the other Lender, (vii) receipt of any notice or request from any Governmental Authority or governmental payor regarding any liability or claim of liability, (viii) receipt of any notice by Borrower regarding termination of any manager of any facility owed, operated or leased by Borrower, (ix) Borrower's execution and delivery of a new contract with a Governmental Authority, providing Lender with an executed copy of such contract promptly thereafter, and/or (x) any Account becoming evidenced or secured by an Instrument or Chattel Paper.

(d) Consents. Borrower shall obtain and deliver from time to time all required consents, approvals and agreements from such third parties as Lender shall determine are necessary or desirable in its Permitted Discretion, each of which must be satisfactory to Lender in its Permitted Discretion, with respect to (i) the Loan Documents and the transactions

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contemplated thereby, (ii) claims against Borrower or the Collateral, and/or (iii) any agreements, consents, documents or instruments to which Borrower is a party or by which any properties or assets of Borrower or any of the Collateral is or are bound or subject, including, without limitation, Landlord Waivers and Consents with respect to leases.

(e) Operating Budget. Borrower shall furnish to Lender on or prior to the Closing Date and for each fiscal year of Borrower thereafter not less than ten (10) calendar days prior to the commencement of such fiscal year, consolidated and consolidating month by month projected operating budgets, annual projections, profit and loss statements, balance sheets and cash flow reports of and for Borrower for such upcoming fiscal year (including an income statement for each month and a balance sheet as at the end of the last month in each fiscal quarter), in each case prepared in accordance with GAAP consistently applied with prior periods.

6.2 Payment of Obligations

Borrower shall make full and timely indefeasible payment in cash of the principal of and interest on the Loans, Advances and all other Obligations.

6.3 Conduct of Business and Maintenance of Existence and Assets

Borrower shall (i) conduct its business in accordance with good business practices customary to the industry, (ii) engage principally in the same or similar lines of business substantially as heretofore conducted, (iii) collect its Accounts in the ordinary course of business, (iv) maintain all of its material properties, assets and equipment used or useful in its business in good repair, working order and condition (normal wear and tear excepted and except as may be disposed of in the ordinary course of business and in accordance with the terms of the Loan Documents and otherwise as determined by Borrower using commercially reasonable business judgment), (v) from time to time to make all necessary or desirable repairs, renewals and replacements thereof, as determined by Borrower using commercially reasonable business judgment, (vi) maintain and keep in full force and effect its existence and all material Permits and qualifications to do business and good standing in each jurisdiction in which the ownership or lease of property or the nature of its business makes such Permits or qualification necessary and in which failure to maintain such Permits or qualification could reasonably be likely to have a Material Adverse Effect; and (vii) remain in good standing in all jurisdictions in which its operations are located.

6.4 Compliance with Legal and Other Obligations

Borrower shall (i) comply with all laws, statutes, rules, regulations, ordinances and tariffs of all Governmental Authorities applicable to it or its business, assets or operations, including applicable requirements of the Standards for Privacy of Individually Identifiable Health Information which were promulgated pursuant to HIPAA; (ii) pay when due all taxes, assessments, fees, governmental charges, claims for labor, supplies, rent and all other obligations or liabilities of any kind, except liabilities being contested in good faith and against which adequate reserves have been established in accordance with GAAP, (iii) perform in accordance with its terms each contract, agreement or other arrangement to which it is a party or by which it or any of the Collateral is bound, except where the failure to comply, pay or perform could not reasonably be expected to have a Material Adverse Effect, and (iv) maintain and comply with all Permits necessary to conduct its business and comply with any new or additional requirements that may be imposed on it or its business.

6.5 Insurance

Borrower shall (i) keep all of its insurable properties and assets adequately insured in all material respects against losses, damages and hazards as are customarily insured against by businesses engaging in similar activities or owning similar assets or properties and at least the minimum amount required by applicable law, and maintain general public liability insurance at all times against liability on account of damage to persons and property having such limits, deductibles, exclusions and co-insurance and other provisions as are customary for a business engaged in activities similar to those of Borrower; and (iii) maintain insurance under all applicable workers' compensation laws; all of the foregoing insurance policies to (A) be reasonably satisfactory in form and substance to Lender, (B) name Lender as additional insured under such insurance as it relates to the Collateral, and (C) expressly provide that they cannot be altered, amended, modified or canceled without thirty (30) Business Days prior written notice to Lender and that they inure to the benefit of Lender notwithstanding any action or omission or negligence of or by Borrower or any insured thereunder.

6.6 True Books

Borrower shall (i) keep true, complete and accurate books of record and account in accordance with commercially reasonable business practices in which true and correct entries are made of all of its and their dealings and transactions in all material respects; and (ii) set up and maintain on its books such reserves as may be required by GAAP with respect to doubtful accounts and all taxes, assessments, charges, levies and claims and with respect to its business, and include such reserves in its quarterly as well as year end financial statements.

6.7 Inspection; Periodic Audits

Borrower shall permit the representatives of Lender, at the expense of Borrower, from time to time during normal business hours upon reasonable notice and in such a manner so as not to unreasonably disrupt any Borrower's operations, to (i) visit and inspect any of its offices or properties or any other place where Collateral is located to inspect the Collateral and/or to examine or audit all of its books of account, records, reports and other papers, (ii) make copies and extracts therefrom, and (iii) discuss its business, operations, prospects, properties, assets, liabilities, condition and/or Accounts with its officers and independent public accountants (and by this provision such officers and accountants are authorized to discuss the foregoing). Other than during the occurrence and continuance of a Default or an Event of Default, not more than four (4) such inspections or audits related to any 12-month period shall be at the expense of Borrower. Lender may increase the frequency of inspections or audits during the occurrence and continuance of a Default or an Event of Default.

6.8 Further Assurances; Post Closing

At Borrower's cost and expense, Borrower shall (i) take such further actions, obtain such consents and approvals and duly execute and deliver such further agreements, assignments, instructions or documents as Lender may reasonably request with respect to the purposes, terms and conditions of the Loan Documents and the consummation of the transactions contemplated thereby, and (ii) without limiting and notwithstanding any other provision of any Loan Document, execute and deliver, or cause to be executed and delivered, such agreements and documents, and take or cause to be taken such actions, and otherwise perform, observe and comply with such obligations, as are set forth on Schedule 6.8.

6.9 Payment of Indebtedness

Except as otherwise prescribed in the Loan Documents, Borrower shall pay, discharge or otherwise satisfy at or before

maturity (subject to applicable grace periods and, in the case of trade payables, to ordinary course payment practices) all of its material obligations and liabilities, except when the amount or validity thereof is being contested in good faith by appropriate proceedings and such reserves as Lender may deem proper and necessary in its sole discretion shall have been made.

6.10 Lien Searches

If Liens other than Permitted Liens exist, Borrower immediately shall take, execute and deliver all actions, documents and instruments necessary to release and terminate such Liens.

6.11 Use of Proceeds

Borrower shall use the proceeds from the Revolving Facility only for the purposes set forth in the first "WHEREAS" clause of this Agreement.

6.12 Collateral Documents; Security Interest in Collateral

Borrower shall (i) execute, obtain, deliver, file, register and/or record any and all financing statements, continuation statements, stock powers, instruments and other documents, or cause the execution, filing, registration, recording or delivery of any and all of the foregoing, that are necessary or required under law or otherwise or reasonably requested by Lender to be executed, filed, registered, obtained, delivered or recorded to create, maintain, perfect, preserve, validate or otherwise protect the pledge of the Collateral to Lender and Lender's perfected first priority Lien on the Collateral (and Borrower irrevocably grants Lender the right, at Lender's option, to file any or all of the foregoing), (ii) immediately upon learning thereof, report to Lender any reclamation, return or repossession of goods in excess of $10,000.00 (individually or in the aggregate), and (iii) defend the Collateral and Lender's perfected first priority Lien thereon against all claims and demands of all Persons at any time claiming the same or any interest therein adverse to Lender, and pay all reasonable costs and expenses (including, without limitation, in-house documentation and diligence fees and legal expenses and reasonable attorneys' fees and expenses) in connection with such defense, which may at Lender's discretion be added to the Obligations.

6.13 Intentionally Deleted

6.14 Taxes and Other Charges

(a) All payments and reimbursements to Lender made under any Loan Document shall be free and clear of and without deduction for all taxes, levies, imposts, deductions, assessments, charges or withholdings, and all liabilities with respect thereto of any nature whatsoever, excluding taxes to the extent imposed on Lender's net income. If Borrower shall be required by law to deduct any such amounts from or in respect of any sum payable under any Loan Document to Lender, then the sum payable to Lender shall be increased as may be necessary so that, after making all required deductions, Lender receives an amount equal to the sum it would have received had no such deductions been made. Notwithstanding any other

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provision of any Loan Document, if at any time after the Closing (i) any change in any existing law, regulation, treaty or directive or in the interpretation or application thereof, (ii) any new law, regulation, treaty or directive enacted or any interpretation or application thereof, or (iii) compliance by Lender with any request or directive (whether or not having the force of law) from any Governmental Authority: (A) subjects Lender to any tax, levy, impost, deduction, assessment, charge or withholding of any kind whatsoever with respect to any Loan Document, or changes the basis of taxation of payments to Lender of any amount payable thereunder (except for net income taxes, or franchise taxes imposed in lieu of net income taxes, imposed generally by federal, state or local taxing authorities with respect to interest or commitment fees or other fees payable hereunder or changes in the rate of tax on the overall net income of Lender), or (B) imposes on Lender any other condition or increased cost in connection with the transactions contemplated thereby or participations therein; and the result of any of the foregoing is to increase the cost to Lender of making or continuing any Loan hereunder or to reduce any amount receivable hereunder, then, in any such case, Borrower shall promptly pay to Lender any additional amounts necessary to compensate Lender, on an after-tax basis, for such additional cost or reduced amount as determined by Lender. If Lender becomes entitled to claim any additional amounts pursuant to this Section 6.14 it shall promptly notify Borrower of the event by reason of which Lender has become so entitled, and each such notice of additional amounts payable pursuant to this Section 6.14 submitted by Lender to Borrower shall, absent manifest error, be final, conclusive and binding for all purposes.

(b) Borrower shall promptly, and in any event within five (5) Business Days after Borrower or any authorized officer of Borrower obtains knowledge thereof, notify Lender in writing of any oral or written communication from the Internal Revenue Service or otherwise with respect to any (i) tax investigations, relating to the Borrower directly, or relating to any consolidated tax return which was filed on behalf of Borrower, (ii) notices of tax assessment or possible tax assessment, (iii) years that are designated open pending tax examination or audit, and (iv) information that could give rise to an IRS tax liability or assessment.

6.15 Payroll Taxes

Without limiting or being limited by any other provision of any Loan Document, Borrower at all times shall retain and use a Person reasonably acceptable to Lender to process, manage and pay its payroll taxes and shall cause to be delivered to Lender within ten (10) calendar days after the end of each calendar month a report of its payroll taxes for the immediately preceding calendar month and evidence of payment thereof.

VII. NEGATIVE COVENANTS

Each Borrower, jointly and severally, covenants and agrees that, until full performance and satisfaction, and indefeasible payment in full in cash, of all of the Obligations and termination of this Agreement:

7.1 Financial Covenants

Borrower shall not violate the financial covenants set forth on Annex I to this Agreement, which is incorporated herein and made a part hereof.

7.2 Permitted Indebtedness

Borrower shall not create, incur, assume or suffer to exist any Indebtedness, except the following (collectively, **"Permitted Indebtedness"**): (i) Indebtedness under the Loan Documents, (ii) any Indebtedness set forth on Schedule 7.2, (iii) Capitalized Lease Obligations incurred after the Closing Date and Indebtedness incurred pursuant to purchase money Liens permitted by Section 7.3(v), provided that the aggregate amount of such Capitalized Lease Obligations and purchase money indebtedness outstanding at any time shall not exceed $100,000, (iv) Indebtedness in connection with advances made by a stockholder in order to cure any default of the financial covenants set forth on Annex I; provided, however, that such Indebtedness shall be on an unsecured basis or secured by assets unrelated to the Collateral, subordinated in right of repayment and remedies to all of the Obligations and to all of Lender's rights pursuant to a subordination agreement in form and substance satisfactory to Lender; (v) accounts payable to trade creditors and current operating expenses (other than for borrowed money) which are not aged more than 120 calendar days from the billing date or more than 30 days from the due date, in each case incurred in the ordinary course of business and paid within such time period, unless the same are being contested in good faith and by appropriate and lawful proceedings and such reserves, if any, with respect thereto as are required by GAAP and deemed adequate by Borrower's independent accountants shall have been reserved; and (vi) borrowings incurred in the ordinary course of business and not exceeding $100,000 individually or in the aggregate outstanding at any one time, provided, however, that such Indebtedness shall be on an unsecured basis or secured by assets other than the Collateral, subordinated in right of repayment and remedies to all of the Obligations and to all of Lender's rights pursuant to a subordination agreement in form and substance satisfactory to Lender. Borrower shall not make prepayments on any existing or future Indebtedness to any Person other than to Lender or to the extent specifically permitted by this Agreement or any subsequent agreement between Borrower and Lender).

7.3 Permitted Liens

Borrower shall not create, incur, assume or suffer to exist any Lien upon, in or against, or pledge of, any of the Collateral or any of its properties or assets or any of its shares, securities or other equity or ownership or partnership interests, whether now owned or hereafter acquired, except the following (collectively, **"Permitted Liens"**): (i) Liens under the Loan Documents or otherwise arising in favor of Lender, (ii) Liens imposed by law for taxes (other than payroll taxes), assessments or charges of any Governmental Authority for claims not yet due or which are being contested in good faith by appropriate proceedings and with respect to which adequate reserves or other appropriate provisions are being maintained by such Person in accordance with GAAP to the satisfaction of Lender in its Permitted Discretion, (iii) (A) statutory Liens of landlords (provided that any such landlord has executed a Landlord Waiver and Consent in form and substance satisfactory to Lender) and of carriers, warehousemen, mechanics, materialmen, and (B) other Liens imposed by law or that arise by operation of law in the ordinary course of business from the date of creation thereof, in each case only for amounts not yet due or which are being contested in good faith by appropriate proceedings and with respect to which adequate reserves or other appropriate provisions are being maintained by such Person in accordance with GAAP to the satisfaction of Lender in its Permitted Discretion, (iv) Liens (A) incurred or deposits made in the ordinary course of business (including, without limitation, surety bonds and appeal bonds) in connection with workers' compensation, unemployment insurance and other types of social security benefits or to secure the performance of tenders, bids, leases, contracts (other than for the repayment of Indebtedness), statutory obligations and other similar obligations, or (B) arising as a result of progress payments under government contracts, (v) purchase money Liens (A) securing Indebtedness permitted under Section 7.2(iii), or (B) in connection with the purchase by such Person of equipment in the normal course of business,

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provided that such payables shall not exceed any limits on Indebtedness provided for herein and shall otherwise be Permitted Indebtedness hereunder, (vi) Liens securing Permitted Mortgage Indebtedness, provided, that such Liens shall not extend to any Collateral and Lender and the Mortgagee shall have entered into a satisfactory intercreditor agreement, and (vii) Liens disclosed on Schedule 7.3.

7.4 Investments; New Facilities or Collateral; Subsidiaries

Except as provided in Schedule 7.4, Borrower, directly or indirectly, shall not, without Lender's prior written consent (i) purchase, own, hold, invest in or otherwise acquire obligations or stock or securities of, or any other interest in, or all or substantially all of the assets of, any Person or any joint venture, or (ii) make or permit to exist any loans, advances or guarantees to or for the benefit of any Person or assume, guarantee, endorse, contingently agree to purchase or otherwise become liable for or upon or incur any obligation of any Person (other than those created by the Loan Documents and Permitted Indebtedness and other than (A) trade credit extended in the ordinary course of business, (B) advances for business travel and similar temporary advances made in the ordinary course of business to officers, directors and employees, and (C) the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business). Borrower, directly or indirectly, shall not purchase, own, operate, hold, invest in or otherwise acquire any facility, property or assets or any Collateral that is not located at the locations set forth on Schedule 5.18B unless Borrower shall provide to Lender at least thirty (30) Business Days prior written notice. Borrower shall have no Subsidiaries other than those Subsidiaries, if any, existing at Closing and set forth in Schedule 5.3.

7.5 Dividends; Redemptions

Borrower shall not (i) declare, pay or make any dividend or distribution on any shares of capital stock or other securities or interests (other than dividends or distributions payable in its stock, or split-ups or reclassifications of its stock), (ii) apply any of its funds, property or assets to the acquisition, redemption or other retirement of any capital stock or other securities or interests or of any options to purchase or acquire any of the foregoing (provided, however, that Borrower may redeem its capital stock from terminated employees pursuant to, but only to the extent required under, the terms of the related employment agreements as long as no Default or Event of Default has occurred and is continuing or would be caused by or result therefrom), (iii) otherwise make any payments or Distributions to any stockholder, member, partner or other equity owner in such Person's capacity as such, or (iv) make any payment of any management or service fee, provided that Borrower shall not make or suffer to exist any such payment described in (i) through (iv) above if a Default of Event of Default has occurred and is continuing or would result therefrom.

7.6 Transactions with Affiliates

Borrower shall not enter into or consummate any transaction of any kind with any of its Affiliates (for purposes of this Section 7.6, Affliliates shall specifically exclude other Borrowers) or any Guarantor or any of their respective Affiliates other than: (i) salary, bonus, employee stock option and other compensation and employment arrangements with employees, directors or officers in the ordinary course of business, provided, that no payment of any bonus shall be permitted if a Default or Event of Default has occurred and remains in effect or would be caused by or result from such payment, (ii) distributions and dividends permitted pursuant to Section 7.4, (iii) transactions with Lender or any Affiliate of Lender, and (iv) payments permitted under and pursuant to written agreements entered into by and between Borrower and one or more

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of its Affiliates that both (A) reflect and constitute transactions on overall terms at least as favorable to Borrower as would be the case in an arm's-length transaction between unrelated parties of equal bargaining power, and (B) are subject to such terms and conditions as determined by Lender in its Permitted Discretion; provided, that notwithstanding the foregoing but subject to the rights under Section 7.2, Borrower shall not (Y) enter into or consummate any transaction or agreement pursuant to which it becomes a party to any mortgage, note, indenture or guarantee evidencing any Indebtedness of any of its Affiliates or otherwise to become responsible or liable, as a guarantor, surety or otherwise, pursuant to agreement for any Indebtedness of any such Affiliate, or (Z) make any payment to any of its Affiliates in excess of $10,000 without the prior written consent of Lender.

7.7 Charter Documents; Fiscal Year; Name; Jurisdiction of Organization; Dissolution; Use of Proceeds

Borrower shall not (i) amend, modify, restate or change its certificate of incorporation or formation or bylaws or similar charter documents in a manner that would be adverse to Lender, (ii) change its fiscal year unless Borrower demonstrates to Lender's satisfaction compliance with the covenants contained herein for both the fiscal year in effect prior to any change and the new fiscal year period by delivery to Lender of appropriate interim and annual pro forma, historical and current compliance certificates for such periods and such other information as Lender may reasonably request, (iii) without at least 20 days prior written notice to Lender, change it's name or change its jurisdiction of organization; (iv) amend, alter or suspend or terminate or make provisional in any material way, any material Permit without the prior written consent of Lender, which consent shall not be unreasonably withheld, (v) wind up, liquidate or dissolve (voluntarily or involuntarily) or commence or suffer any proceedings seeking or that would result in any of the foregoing, or (vi) use any proceeds of any Advance for "purchasing" or "carrying" "margin stock" as defined in Regulations U, T or X of the Board of Governors of the Federal Reserve System.

7.8 Truth of Statements

Borrower shall not furnish to Lender any certificate or other document that contains any untrue statement of a material fact or that omits to state a material fact necessary to make it not misleading in light of the circumstances under which it was furnished.

7.9 IRS Form 8821

Borrower shall not alter, amend, restate, or otherwise modify, or withdraw, terminate or re-file the IRS Form 8821 required to be filed pursuant to the Conditions Precedent in Section 4.1 hereof.

7.11 Transfer of Assets

Notwithstanding any other provision of this Agreement or any other Loan Document, Borrower shall not sell, lease, transfer, assign or otherwise dispose of any interest in any properties or assets (other than obsolete equipment or excess equipment no longer needed in the conduct of the business in the ordinary course of business, Inventory, scrap, or licenses of General Intangibles in the ordinary course of business), or agree to do any of the foregoing at any future time, except that:

(a) Borrower may lease (as lessee) real or personal property or surrender all or a portion of a lease of the same, in each case in the ordinary course of business (so long as such lease does not create or result in and is not otherwise a Capitalized Lease Obligation prohibited under this Agreement), provided that a Landlord Waiver and Consent and such other consents as are required by Lender are signed and delivered to Lender with respect to any lease of real or other property, as applicable;

(b) Borrower may consummate such other sales or dispositions of property or assets (including any sale or transfer or disposition of all or any part of its assets and thereupon and within one year thereafter rent or lease the assets so sold or transferred) only to the extent prior written notice has been given to Lender and to the extent Lender has given its prior written consent thereto, subject in each case to such conditions as may be set forth in such consent.

VIII. EVENTS OF DEFAULT

The occurrence of any one or more of the following shall constitute an "Event of Default:"

(a) Borrower shall fail to pay any amount on the Obligations or provided for in any Loan Document when due (whether on any payment date, at maturity, by reason of acceleration, by notice of intention to prepay, by required prepayment or otherwise);

(b) any representation, statement or warranty made or deemed made by Borrower or any Guarantor in any Loan Document or in any other certificate, document, report or opinion delivered in conjunction with any Loan Document to which it is a party, shall not be true and correct in all material respects or shall have been false or misleading in any material respect on the date when made or deemed to have been made (except to the extent already qualified by materiality, in which case it shall be true and correct in all respects and shall not be false or misleading in any respect);

(c) Borrower or any Guarantor or other party thereto other than Lender shall be in violation, breach or default of, or shall fail to perform, observe or comply with any covenant, obligation or agreement set forth in, any Loan Document and such violation, breach, default or failure shall not be cured within the applicable period set forth in the applicable Loan Document; provided that, with respect to the affirmative covenants set forth in Article VI (other than Sections 6.1(c), 6.2, 6.3(i), (ii) and (iii), 6.5, 6.8, 6.9 and 6.11 for which there shall be no cure period), there shall be a fifteen (15) calendar day cure period commencing from the earlier of (i) Receipt by such Person of written notice of such breach, default, violation or failure, and (ii) the time at which such Person or any authorized officer thereof knew or became aware of such failure, violation, breach or default but no Advances will be made during the cure period;

(d) (i) any of the Loan Documents ceases to be in full force and effect except for a Termination as provided for herein, or (ii) any Lien created thereunder ceases to constitute a valid perfected first priority Lien on the Collateral in accordance with the terms thereof, or Lender ceases to have a valid perfected first priority security interest in any of the Collateral or any securities pledged to Lender pursuant to the Security Documents;

(e) one or more tax assessments, judgments or decrees is rendered against any Borrower or Guarantor in an amount in excess of $10,000 individually or $50,000 in the

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aggregate, which is/are not satisfied, stayed, vacated or discharged of record within thirty (30) calendar days of being rendered but no Advances will be made before the judgment is stayed, vacated or discharged;

(f) (i) any default occurs, which is not cured or waived, (x) in the payment of any amount with respect to any Indebtedness (other than the Obligations) of any Borrower or Guarantor in excess of $10,000, (y) in the performance, observance or fulfillment of any provision contained in any agreement, contract, document or instrument to which any Borrower or Guarantor is a party or to which any of their properties or assets are subject or bound under or pursuant to which any Indebtedness was issued, created, assumed, guaranteed or secured and such default continues for more than any applicable grace period or permits the holder of any Indebtedness to accelerate the maturity thereof, or (z) in the performance, observance or fulfillment of any provision contained in any agreement, contract, document or instrument between any Borrower or Guarantor and Lender or any Affiliate of Lender (other than the Loan Documents), or (ii) any Indebtedness in excess of $25,000 of any Borrower or Guarantor is declared to be due and payable or is required to be prepaid (other than by a regularly scheduled payment) prior to the stated maturity thereof, or any obligation of such Person for the payment of Indebtedness (other than the Obligations) is not paid when due or within any applicable grace period, or any such obligation becomes or is declared to be due and payable before the expressed maturity thereof, or there occurs an event which, with the giving of notice or lapse of time, or both, would cause any such obligation to become, or allow any such obligation to be declared to be, due and payable;

(g) any Borrower or Guarantor shall (i) be unable to pay its debts generally as they become due, (ii) have total liabilities (including contingent, subordinated, unmatured and unliquidated liabilities) that exceed its assets, at a Fair Valuation, (iii) file a petition under any insolvency statute, (iv) make a general assignment for the benefit of its creditors, (v) commence a proceeding for the appointment of a receiver, trustee, liquidator or conservator of itself or of the whole or any substantial part of its property, or (vi) file a petition seeking reorganization or liquidation or similar relief under any Debtor Relief Law or any other applicable law or statute;

(h) a court of competent jurisdiction shall (A) enter an order, judgment or decree appointing a custodian, receiver, trustee, liquidator or conservator of any Borrower or Guarantor or the whole or any substantial part of any such Person's properties, which shall continue unstayed and in effect for a period of thirty (30) calendar days, (B) shall approve a petition filed against any Borrower or Guarantor seeking reorganization, liquidation or similar relief under the any Debtor Relief Law or any other applicable law or statute, which is not dismissed within thirty (30) calendar days or, (C) under the provisions of any Debtor Relief Law or other applicable law or statute, assume custody or control of any Borrower or Guarantor or of the whole or any substantial part of any such Person's properties, which is not irrevocably relinquished within thirty (30) calendar days, or (ii) there is commenced against any Borrower or Guarantor any proceeding or petition seeking reorganization, liquidation or similar relief under any Debtor Relief Law or any other applicable law or statute and either (A) any such proceeding or petition is not unconditionally dismissed within thirty (30) calendar days after the date of commencement, or (B) any Borrower or Guarantor takes any action to indicate its approval of or consent to any such proceeding or petition, but no Advances will be made before any such order, judgment or decree described above is stayed, vacated or discharged, any such petition described above is dismissed, or any such custody or control described above is relinquished;

(i) (i) any Change of Control occurs or any agreement or commitment to cause or that may result in any such Change of Control is entered into, (ii) any Material Adverse Effect or Material Adverse Change occurs or is reasonably expected to occur,

or (iii) any Borrower or Guarantor ceases a material portion of its business operations as currently conducted;

(j) Lender receives any evidence that any Borrower or Guarantor may have directly or indirectly been engaged in any type of activity which, in Lender's reasonable judgment, is likely to result in forfeiture of any property to any Governmental Authority which shall have continued unremedied for a period of ten (10) calendar days after written notice from Lender (but no Advances will be made before any such activity ceases);

(k) an Event of Default occurs under any other Loan Document;

(l) uninsured damage to, or loss, theft or destruction of, any portion of the Collateral occurs that exceeds $10,000 in the aggregate;

(m) any Borrower or Guarantor or any of their respective directors or senior officers is criminally indicted or convicted under any law that could lead to a forfeiture of any Collateral;

(n) the issuance of any process for levy, attachment or garnishment or execution upon or prior to any judgment against any Borrower or Guarantor or any of their property or assets; or

(o) any Borrower or Guarantor does, or enters into or becomes a party to any agreement or commitment to do, or cause to be done, any of the things described in this Article VIII or otherwise prohibited by any Loan Document (subject to any cure periods set forth therein);

then, and in any such event, notwithstanding any other provision of any Loan Document, Lender may, without notice or demand, do any of the following: (i) terminate its obligations to make Advances hereunder, whereupon the same shall immediately terminate and (ii) declare all or any of the Notes, all interest thereon and all other Obligations to be due and payable immediately (except in the case of an Event of Default under Section 8(d), (g), (h) or (i)(iii), in which event all of the foregoing shall automatically and without further act by Lender be due and payable, provided that, with respect to non-material breaches or violations that constitute Events of Default under clause (ii) of Section 8(d), there shall be a three (3) Business Day cure period (but no Advances will be made during any such cure period) commencing from the earlier of (A) Receipt by the applicable Person of written notice of such breach or violation or of any event, fact or circumstance constituting or resulting in any of the foregoing, and (B) the time at which such Person or any authorized officer thereof knew or became aware, or should have known or been aware, of such breach or violation and resulting Event of Default or of any event, fact or circumstance constituting or resulting in any of the foregoing), in each case without presentment, demand, protest or further notice of any kind, all of which are hereby expressly waived by Borrower.

IX. RIGHTS AND REMEDIES AFTER DEFAULT

9.1 Rights and Remedies

(a) In addition to the acceleration provisions set forth in Article VIII above, upon the occurrence and continuation of an Event of Default, Lender shall have the right to exercise any and all rights, options and remedies provided for in the Loan Documents, under the UCC or at law or in equity, including, without limitation, the right to (i) apply any property of any Borrower held by Lender to reduce the Obligations, (ii) foreclose the Liens created under the Security Documents, (iii) realize upon, take possession of and/or sell any Collateral or securities

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pledged with or without judicial process, (iv) exercise all rights and powers with respect to the Collateral as any Borrower, as applicable, might exercise, (v) collect and send notices regarding the Collateral, with or without judicial process, (vi) by its own means or with judicial assistance, enter any premises at which Collateral and/or pledged securities are located, or render any of the foregoing unusable or dispose of the Collateral and/or pledged securities on such premises without any liability for rent, storage, utilities, or other sums, and no Borrower shall resist or interfere with such action, (vii) at Borrower's expense, require that all or any part of the Collateral be assembled and made available to Lender at any place designated by Lender, (viii) reduce or otherwise change the Facility Cap, and/or (ix) relinquish or abandon any Collateral or securities pledged or any Lien thereon. Notwithstanding any provision of any Loan Document, Lender, in its sole discretion, shall have the right, at any time that Borrower fails to do so, and from time to time, without prior notice, to: (i) obtain insurance covering any of the Collateral to the extent required hereunder; (ii) pay for the performance of any of the Obligations; (iii) discharge taxes or Liens on any of the Collateral that are in violation of any Loan document unless Borrower is in good faith with due diligence by appropriate proceedings contesting those items; and (iv) pay for the maintenance and preservation of the Collateral. Such expenses and advances shall be added to the Obligations until reimbursed to Lender and shall be secured by the Collateral, and such payments by Lender shall not be construed as a waiver by Lender of any Event of Default or any other rights or remedies of Lender.

(b) Borrower agrees that notice received by it at least ten (10) calendar days before the time of any intended public sale, or the time after which any private sale or other disposition of Collateral is to be made, shall be deemed to be reasonable notice of such sale or other disposition. If permitted by applicable law, any perishable Collateral which threatens to speedily decline in value or which is sold on a recognized market may be sold immediately by Lender without prior notice to Borrower. At any sale or disposition of Collateral or securities pledged, Lender may (to the extent permitted by applicable law) purchase all or any part thereof free from any right of redemption by any Borrower which right is hereby waived and released. Borrower covenants and agrees not to, and not to permit or cause any of its Subsidiaries to, interfere with or impose any obstacle to Lender's exercise of its rights and remedies with respect to the Collateral. Lender, in dealing with or disposing of the Collateral or any part thereof, shall not be required to give priority or preference to any item of Collateral or otherwise to marshal assets or to take possession or sell any Collateral with judicial process.

9.2 Application of Proceeds

In addition to any other rights, options and remedies Lender has under the Loan Documents, the UCC, at law or in equity, all dividends, interest, rents, issues, profits, fees, revenues, income and other proceeds collected or received from collecting, holding, managing, renting, selling, or otherwise disposing of all or any part of the Collateral or any proceeds thereof upon exercise of its remedies hereunder shall be applied in the following order of priority: (i) first, to the payment of all costs and expenses of such collection, storage, lease, holding, operation, management, sale, disposition or delivery and of conducting Borrower's business and of maintenance, repairs, replacements, alterations, additions and improvements of or to the Collateral, and to the payment of all sums which Lender may be required or may elect to pay, if any, for taxes, assessments, insurance and other charges upon the Collateral or any part thereof, and all other payments that Lender may be required or authorized to make under any provision of this Agreement (including, without limitation, in each such case, in-house documentation and diligence fees and legal expenses, search, audit, recording, professional and filing fees and expenses and reasonable attorneys' fees and all expenses, liabilities and advances made or incurred in connection therewith); (ii) second, to the payment of all Obligations as provided

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herein; (iii) third, to the satisfaction of Indebtedness secured by any subordinate security interest of record in the Collateral if written notification of demand therefor is received before distribution of the proceeds is completed, provided, that, if requested by Lender, the holder of a subordinate security interest shall furnish reasonable proof of its interest, and unless it does so, Lender need not address its claims; and (iv) fourth, to the payment of any surplus then remaining to Borrower, unless otherwise provided by law or directed by a court of competent jurisdiction, provided that Borrower shall be liable for any deficiency if such proceeds are insufficient to satisfy the Obligations or any of the other items referred to in this section.

9.3 Intentionally Deleted

9.4 Rights and Remedies not Exclusive

Lender shall have the right in its sole discretion to determine which rights, Liens and/or remedies Lender may at any time pursue, relinquish, subordinate or modify, and such determination will not in any way modify or affect any of Lender's rights, Liens or remedies under any Loan Document, applicable law or equity. The enumeration of any rights and remedies in any Loan Document is not intended to be exhaustive, and all rights and remedies of Lender described in any Loan Document are cumulative and are not alternative to or exclusive of any other rights or remedies which Lender otherwise may have. The partial or complete exercise of any right or remedy shall not preclude any other further exercise of such or any other right or remedy.

X. WAIVERS AND JUDICIAL PROCEEDINGS

10.1 Waivers

Except as expressly provided for herein, Borrower hereby waives setoff, counterclaim, demand, presentment, protest, all defenses with respect to any and all instruments and all notices and demands of any description, and the pleading of any statute of limitations as a defense to any demand under any Loan Document. Borrower hereby waives any and all defenses and counterclaims it may have or could interpose in any action or procedure brought by Lender to obtain an order of court recognizing the assignment of, or Lien of Lender in and to, any Collateral. With respect to any action hereunder, Lender conclusively may rely upon, and shall incur no liability to Borrower in acting upon, any request or other communication that Lender reasonably believes to have been given or made by a person authorized on Borrower's behalf, whether or not such person is listed on the incumbency certificate delivered pursuant to Section 4.1 hereof. In each such case, Borrower hereby waives the right to dispute Lender's action based upon such request or other communication, absent manifest error.

10.2 Delay; No Waiver of Defaults

No course of action or dealing, renewal, release or extension of any provision of any Loan Document, or single or partial exercise of any such provision, or delay, failure or omission on Lender's part in enforcing any such provision shall affect the liability of any Borrower or Guarantor or operate as a waiver of such provision or affect the liability of any Borrower or Guarantor or preclude any other or further exercise of such provision. No waiver by any party to any Loan Document of any one or more defaults by any other party in the performance of any of the provisions of any Loan Document shall operate or be construed as a waiver of any future default, whether of a like or different nature, and each such waiver shall be limited solely to the express terms and provisions of such waiver. Notwithstanding any other

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provision of any Loan Document, by completing the Closing under this Agreement and/or by making Advances, Lender does not waive any breach of any representation or warranty under any Loan Document, and all of Lender's claims and rights resulting from any such breach or misrepresentation are specifically reserved.

10.3 Jury Waiver

EACH PARTY TO THIS AGREEMENT HEREBY EXPRESSLY WAIVES ANY RIGHT TO TRIAL BY JURY OF ANY CLAIM OR CAUSE OF ACTION ARISING UNDER THE LOAN DOCUMENTS OR IN ANY WAY CONNECTED WITH OR INCIDENTAL TO THE DEALINGS OF THE PARTIES WITH RESPECT TO THE LOAN DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED THEREBY, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN

CONTRACT, TORT OR OTHERWISE. EACH PARTY HEREBY AGREES AND CONSENTS THAT ANY SUCH CLAIM OR CAUSE OF ACTION SHALL BE DECIDED BY COURT TRIAL WITHOUT A JURY, AND THAT ANY PARTY TO THIS AGREEMENT MAY FILE AN ORIGINAL COUNTERPART OR A COPY OF THIS SECTION WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENTS OF THE PARTIES TO THE WAIVER OF THEIR RESPECTIVE RIGHTS TO TRIAL BY JURY.

10.4 Cooperation in Discovery and Litigation

In any litigation, arbitration or other dispute resolution proceeding relating to any Loan Document, Borrower waives any and all defenses, objections and counterclaims it may have or could interpose with respect to (i) any of its directors, officers, employees or agents being deemed to be employees or managing agents of Borrower for purposes of all applicable law or court rules regarding the production of witnesses by notice for testimony (whether in a deposition, at trial or otherwise), (ii) Lender's counsel examining any such individuals as if under cross-examination and using any discovery deposition of any of them as if it were an evidence deposition, and/or (iii) using all commercially reasonable efforts to produce in any such dispute resolution proceeding, at the time and in the manner requested by Lender, all Persons, documents (whether in tangible, electronic or other form) and/or other things under its control and relating to the dispute.

XI. EFFECTIVE DATE AND TERMINATION

11.1 Termination and Effective Date Thereof

(a) Subject to Lender's right to terminate and cease making Advances upon or after any Event of Default, this Agreement shall continue in full force and effect until the full performance and indefeasible payment in cash of all Obligations, unless terminated sooner as provided in this Section 11.1. Borrower may terminate this Agreement at any time upon not less than sixty (60) calendar days' prior written notice to Lender and upon full performance and indefeasible payment in full in cash of all Obligations on or prior to such 60th calendar day after Receipt by Lender of such written notice. All of the Obligations shall be immediately due and payable upon any such termination on the termination date stated in any notice of termination (the **"Termination Date"**); provided that, notwithstanding any other provision of any Loan Document, the Termination Date shall be effective no earlier than the first Business Day of the month following the expiration of the sixty (60) calendar days' prior written notice period. Notwithstanding any other provision of any Loan Document, no termination of this Agreement shall affect Lender's rights or any of the Obligations existing as of the effective date of such termination, and the provisions of the Loan Documents shall continue to be fully operative until the Obligations have been fully performed and indefeasibly paid in cash in full. The Liens granted to Lender under the Security Documents and the financing statements filed pursuant thereto and the rights and powers of Lender shall continue in full force and effect notwithstanding

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the fact that Borrower's borrowings hereunder may from time to time be in a zero or credit position until all of the Obligations have been fully performed and indefeasibly paid in full in cash.

(b) If (i) Borrower terminates the Revolving Facility under this Section 11.1, (ii) Borrower voluntarily or involuntarily repays the Obligations (other than reductions to zero of the outstanding balance of the Revolving Facility resulting from the ordinary course operation of the provisions of Section 2.5), whether by virtue of Lender's exercising its right of set off or otherwise; (iii) the Obligations are accelerated by Lender (each of the events described in (i), (ii) and (iii) above being hereinafter referred to as, a **"Revolver Termination"**), then at the effective date of any such Revolver Termination, Borrower shall pay Lender (in addition to the then outstanding principal, accrued interest and other Obligations relating to the Revolving Facility pursuant to the terms of this Agreement and any other Loan Document), to compensate Lender for the loss of bargain and not as a penalty, an amount equal to the applicable Minimum Termination Fee.

11.2 Survival

All obligations, covenants, agreements, representations, warranties, waivers and indemnities made by Borrower in any Loan Document shall survive the execution and delivery of the Loan Documents, the Closing, the making of the Advances and any termination of this Agreement until all Obligations are fully performed and indefeasibly paid in full in cash. The obligations and provisions of Sections 3.4, 3.5, 6.13, 10.1, 10.3, 11.1, 11.2, 12.4, 12.7 and 12.10 shall survive termination of the Loan Documents and any payment, in full or in part, of the Obligations.

XII. MISCELLANEOUS

12.1 Governing Law; Jurisdiction; Service of Process; Venue

The Loan Documents shall be governed by and construed in accordance with the internal laws of the State of Maryland without giving effect to its choice of law provisions. Any judicial proceeding against Borrower with respect to the Obligations, any Loan Document or any related agreement may be brought in any federal or state court of competent jurisdiction located in the State of Maryland. By execution and delivery of each Loan Document to which it is a party, Borrower (i) accepts the non-exclusive jurisdiction of the aforesaid courts and irrevocably agrees to be bound by any judgment rendered thereby, (ii) waives personal service of process, (iii) agrees that service of process upon it may be made by certified or registered mail, return receipt requested, pursuant to Section 12.5 hereof, (iv) waives any objection to jurisdiction and venue of any action instituted hereunder and agrees not to assert any defense based on lack of jurisdiction, venue or convenience, and (v) agrees that this loan was made in Maryland, that Lender has accepted in Maryland Loan Documents executed by Borrower and has disbursed Advances under the Loan Documents in Maryland. Nothing shall affect the right of Lender to serve process in any manner permitted by law or shall limit the right of Lender to bring proceedings against Borrower in the courts of any other jurisdiction having jurisdiction. Any judicial proceedings against Lender involving, directly or indirectly, the Obligations, any Loan Document or any related agreement shall be brought only in a federal or state court located in the State of

Maryland. All parties acknowledge that they participated in the negotiation and drafting of this Agreement and that, accordingly, no party shall move or petition a court construing this Agreement to construe it more stringently against one party than against any other.

12.2 Successors and Assigns; Participations; New Lenders

The Loan Documents shall inure to the benefit of Lender, Transferees and all future holders of any Note, the Obligations and/or any of the Collateral, and each of their respective successors and assigns. Each Loan Document shall be binding upon the Persons' other than Lender that are parties thereto and their respective successors and assigns, and no such Person may assign, delegate or transfer any Loan Document or any of its rights or obligations thereunder without the prior written consent of Lender. No rights are intended to be created under any Loan Document for the benefit of any third party donee, creditor or incidental beneficiary of any Borrower or Guarantor. Nothing contained in any Loan Document shall be construed as a delegation to Lender of any other Person's duty of performance. BORROWER ACKNOWLEDGES AND AGREES THAT LENDER AT ANY TIME AND FROM TIME TO TIME MAY (I) DIVIDE AND RESTATE ANY NOTE, AND/OR (II) SELL, ASSIGN OR GRANT PARTICIPATING INTERESTS IN OR TRANSFER ALL OR ANY PART OF ITS RIGHTS OR OBLIGATIONS UNDER ANY LOAN DOCUMENT, NOTE, THE OBLIGATIONS AND/OR THE COLLATERAL TO OTHER PERSONS (EACH SUCH TRANSFEREE, ASSIGNEE OR PURCHASER, A **"TRANSFEREE"**). Each Transferee shall have all of the rights and benefits with respect to the Obligations, Notes, Collateral and/or Loan Documents held by it as fully as if the original holder thereof, and either Lender or any Transferee may be designated as the sole agent to manage the transactions and obligations contemplated therein; provided that, notwithstanding anything to the contrary in any Loan Document, Borrower shall not be obligated to pay under this Agreement to any Transferee any sum in excess of the sum which Borrower would have been obligated to pay to Lender had such participation not been effected. Notwithstanding any other provision of any Loan Document, Lender may disclose to any Transferee all information, reports, financial statements, certificates and documents obtained under any provision of any Loan Document.

12.3 Application of Payments

To the extent that any payment made or received with respect to the Obligations is subsequently invalidated, determined to be fraudulent or preferential, set aside or required to be repaid to a trustee, debtor in possession, receiver, custodian or any other Person under any Debtor Relief Law, common law or equitable cause or any other law, then the Obligations intended to be satisfied by such payment shall be revived and shall continue as if such payment had not been received by Lender. Any payments with respect to the Obligations received shall be credited and applied in such manner and order as Lender shall decide in its Permitted Discretion.

12.4 Indemnity

Each Borrower jointly and severally shall indemnify Lender, its Affiliates and its and their respective managers, members, officers, employees, Affiliates, agents, representatives, successors, assigns, accountants and attorneys (collectively, the **"Indemnified Persons"**) from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses and disbursements of any kind or nature whatsoever (including, without limitation, reasonable fees and disbursements of counsel and in-house documentation and diligence fees and legal expenses) which may be imposed on, incurred by or asserted against any Indemnified Person with respect to or arising out of, or in any litigation, proceeding or investigation instituted or conducted by any Person with respect to any aspect of, or any transaction contemplated by or referred to in, or any matter related to, any Loan Document or any agreement, document or transaction contemplated thereby, whether or not such Indemnified Person is a party thereto, except to the extent that any of the foregoing arises out of the gross

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negligence or willful misconduct of such Indemnified Person. If any Indemnified Person uses in-house counsel for any purpose for which any Borrower is responsible to pay or indemnify, each Borrower expressly agrees that its indemnification obligations include reasonable charges for such work commensurate with the fees that would otherwise be charged by outside legal counsel selected by such Indemnified Person in its sole discretion for the work performed. Lender agrees to give Borrower reasonable notice of any event of which Lender becomes aware for which indemnification may be required under this Section 12.4, and Lender may elect (but is not obligated) to direct the defense thereof, provided that the selection of counsel shall be subject to Borrower's consent, which consent shall not be unreasonably withheld or delayed. Any Indemnified Person may, in its reasonable discretion, take such actions as it deems necessary and appropriate to investigate, defend or settle any event or take other remedial or corrective actions with respect thereto as may be necessary for the protection of such Indemnified Person or the Collateral. Notwithstanding the foregoing, if any insurer agrees to undertake the defense of an event (an **"Insured Event"**), Lender agrees not to exercise its right to select counsel to defend the event if that would cause any Borrower's insurer to deny coverage; provided, however, that Lender reserves the right to retain counsel to represent any Indemnified Person with respect to an Insured Event at Lender's sole cost and expense. To the extent that Lender obtains recovery from a third party other than an Indemnified Person of any of the amounts that any Borrower has paid to Lender pursuant to the indemnity set forth in this Section 12.4, then Lender shall promptly pay to such Borrower the amount of such recovery.

12.5 Notice

Any notice or request under any Loan Document shall be given to any party to this Agreement at such party's address set forth beneath its signature on the signature page to this Agreement, or at such other address as such party may hereafter specify in a notice given in the manner required under this Section 12.5. Any notice or request hereunder shall be given only by, and shall be deemed to have been received upon (each, a **"Receipt"**): (i) registered or certified mail, return receipt requested, on the date on which received as indicated in such return receipt, (ii) delivery by a nationally recognized overnight courier, one (1) Business Day after deposit with such courier, or (iii) facsimile transmission, upon telephone or further electronic communication from the recipient acknowledging receipt (whether automatic or manual from recipient), as applicable.

12.6 Severability; Captions; Counterparts; Facsimile Signatures

If any provision of any Loan Document is adjudicated to be invalid under applicable laws or regulations, such provision shall be inapplicable to the extent of such invalidity without affecting the validity or enforceability of the remainder of the Loan Documents which shall be given effect so far as possible. The captions in the Loan Documents are intended for convenience and reference only and shall not affect the meaning or interpretation of the Loan Documents. The Loan Documents may be executed in one or more counterparts (which taken together, as applicable, shall constitute one and the same instrument) and by facsimile transmission, which facsimile signatures shall be considered original executed counterparts. Each party to this Agreement agrees that it will be bound by its own facsimile signature and that it accepts the facsimile signature of each other party.

12.7 Expenses

Borrower shall pay, whether or not the Closing occurs, all costs and expenses incurred by Lender and/or its Affiliates, including, without limitation, documentation and

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diligence fees and expenses, all search, audit, appraisal, recording, professional and filing fees and expenses and all other out-of-pocket charges and expenses (including, without limitation, UCC and judgment and tax lien searches and UCC filings and fees for post-Closing UCC and judgment and tax lien searches and wire transfer fees and audit expenses), and reasonable attorneys' fees and expenses, (i) in any effort to enforce, protect or collect payment of any Obligation or to enforce any Loan Document or any related agreement, document or instrument, (ii) in connection with entering into, negotiating, preparing, reviewing and executing the Loan Documents and/or any related agreements, documents or instruments, (iii) arising in any way out of administration of the Obligations, (iv) in connection with instituting, maintaining, preserving, enforcing and/or foreclosing on Lender's Liens in any of the Collateral or securities pledged under the Loan Documents, whether through judicial proceedings or otherwise, (v) in defending or prosecuting any actions, claims or proceedings arising out of or relating to Lender's transactions with Borrower, (vi) in seeking, obtaining or receiving any advice with respect to its rights and obligations under any Loan Document and any related agreement, document or instrument, and/or (vii) in connection with any modification, restatement, supplement, amendment, waiver or extension of any Loan Document and/or any related agreement, document or instrument. All of the foregoing shall be charged to Borrower's account and shall be part of the Obligations. If Lender or any of its Affiliates uses in-house counsel for any purpose under any Loan Document for which Borrower is responsible to pay or indemnify, Borrower expressly agrees that its Obligations include reasonable charges for such work commensurate with the fees that would otherwise be charged by outside legal counsel selected by Lender or such Affiliate in its sole discretion for the work performed. Without limiting the foregoing, Borrower shall pay all taxes (other than taxes based upon or measured by Lender's income or revenues or any personal property tax), if any, in connection with the issuance of any Note and the filing and/or recording of any documents and/or financing statements.

12.8 Entire Agreement

This Agreement and the other Loan Documents to which Borrower is a party constitute the entire agreement between Borrower and Lender with respect to the subject matter hereof and thereof, and supersede all prior agreements and understandings, if any, relating to the subject matter hereof or thereof. Any promises, representations, warranties or guarantees not herein contained and hereinafter made shall have no force and effect unless in writing signed by Borrower and Lender. No provision of this Agreement may be changed, modified, amended, restated, waived, supplemented, discharged, canceled or terminated orally or by any course of dealing or in any other manner other than by an agreement in writing signed by Lender and Borrower. Each party hereto acknowledges that it has been advised by counsel in connection with the negotiation and execution of this Agreement and is not relying upon oral representations or statements inconsistent with the terms and provisions hereof.

12.9 Lender Approvals

Unless expressly provided herein to the contrary, any approval, consent, waiver or satisfaction of Lender with respect to any matter that is subject of any Loan Document may be granted or withheld by Lender in its sole and absolute discretion.

12.10 Publicity

Borrower hereby agrees that Lender or any Affiliate of Lender may (i) disclose a general description of transactions arising under the Loan Documents for advertising, marketing

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or other similar purposes and (ii) use Borrower's or any Guarantor's name, logo or other indicia germane to such party in connection with such advertising, marketing or other similar purposes.

12.11 Agent

Lender and its successors and assigns hereby (i) designate and appoint CapitalSource Finance LLC, a Delaware limited liability company, and its successors and assigns ("CapitalSource"), to act as agent for Lender and its successors and assigns under this Agreement and all other Loan Documents, (ii) irrevocably authorize CapitalSource to take all actions on its behalf under the provision of this Loan Agreement and all other Loan Documents, and (iii) to exercise all such powers and rights, and to perform all such duties and obligations hereunder and thereunder. CapitalSource, on behalf of Lender, shall hold all Collateral, payments of principal and interest, fees, charges and collections received pursuant to this Agreement and all other Loan Documents. Borrower acknowledges that Lender

and its successors and assigns transfer and assign to CapitalSource the right to act as Lender's agent to enforce all rights and perform all obligations of Lender contained herein and in all of the other Loan Documents. Borrower shall within ten (10) Business Days after Lender's reasonable request, take such further actions, obtain such consents and approvals and duly execute and deliver such further agreements, amendments, assignments, instructions or documents as Lender may request to evidence the appointment and designation of CapitalSource as agent for Lender and other financial institutions from time to time party hereto and to the other Loan Documents.

12.12 Confidentiality/ Restrictions on Securities Transactions

Lender agrees to keep all non-public information confidential and not to disclose or make available any such information to any third parties other than to parties who agree to keep it confidential. Lender acknowledges that the United States securities laws prohibit any person who has material non-public information about a company from purchasing or selling securities of such company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell securities. Lender will not purchase or sell securities of Borrower during any period when Lender possesses material non-public information.

[SIGNATURES APPEAR ON THE FOLLOWING PAGE]

IN WITNESS WHEREOF, each of the parties has duly executed this Revolving Credit and Security Agreement as of the date first written above.

BOSTON BIOMEDICA, INC.
BBI BIOTECH RESEARCH LABORATORIES, INC.
BBI SOURCE SCIENTIFIC, INC.
BBI BIOSEQ, INC.

By: /s/ Kevin W. Quinlan
Name: Kevin W. Quinlan
Its: President & Chief Operating Officer

Address for Notices:
Boston Biomedica, Inc.
375 West Street
West Bridgewater, MN 02379
Attention: President
Telephone: (508) 580-1980
FAX: (508) 580-1110

CAPITALSOURCE FINANCE LLC

By: /s/ Steven A. Museles
Name: Steven A. Museles
Its: Secretary

Address for Notices:
CapitalSource Finance LLC
4445 Willard Avenue, 12th Floor
Chevy Chase, MD 20815

Attention: Healthcare Finance Group, Portfolio Manager

Telephone: (301) 841-2700
FAX: (301) 841-2340

Exhibit 10.31

Boston Biomedica Inc. – Consultant Agreement

This Agreement is entered into as of the 31st day of December, 2003, between Boston Biomedica Inc. ("the Company") and Richard T. Schumacher ("the Consultant").

WHEREAS, the Company desires to assure itself that the benefits of the consulting abilities and talents of the Consultant relative to certain aspects of the Company's business will be available to the Company;

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, it is hereby agreed by and between the parties as follows:

1. Consulting Engagement. Subject to the terms and conditions of this Agreement, the Company hereby extends the current engagement of the Consultant as Executive Project Consultant to perform the services set forth herein, and the Consultant hereby accepts such engagement.

2. Term. The Term of the Consultant's engagement hereunder shall commence on the date hereof and extend through December 31, 2004 unless sooner terminated as hereinafter provided.

3. Duties. Subject to the terms and conditions in this Agreement, the Consultant's duties as Executive Project Consultant shall be to take an advisory role in directing the Company's PCT and Source activities and the Company's ownership interest in Panacos Pharmaceuticals, Inc. ("Panacos"), each as further described below, and such other duties as may be assigned to him by the President of the Company or the Board from time to time. The Consultant shall report to, be specifically accountable to, and shall follow the directions of the Board of Directors of the Company The Consultant shall devote substantially all his business time and energy and will use his best efforts to perform his duties hereunder. The Consultant will be given reasonable access to Company personnel to assist the Consultant in the fulfillment of his duties and responsibilities under this Agreement.

4. Compensation. During the term of the Consultant's engagement under this Agreement, the Consultant shall be paid $4,807.90 per week, which is equivalent to an annualized salary of $250,000.00, prorated for the number of weeks between the date hereof and December 31, 2004 and based on a 52 week year. Such amounts shall be paid periodically in accordance with the Company's normal payroll practices. The Consultant will also be eligible to receive from the Company a performance bonus in recognition of the successful completion of his duties and responsibilities as described herein. The amount of such performance bonus, if any, and the date upon which it will be paid, will be determined by the Board of Directors of the Company in its sole and exclusive discretion. In addition to his salary and bonus, if any, for the sole purpose of determining compensation and benefits, the Consultant shall be considered a full time employee and as such will be entitled to participate in and immediately eligible for health and medical insurance, disability insurance, group life insurance, group travel insurance, and 401(k) retirement plan applicable to all full

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time employees of the Company as they may be in effect from time to time. The Consultant's prior service with the Company shall be attributed to Consultant in determining eligibility to participate in and the extent of benefits from such benefit plans. There shall be no waiting period for participation in any such plan. The Consultant shall be eligible for vacation, holidays and sick days in accordance with the Company's policies applicable to all full time employees.

5. PCT, Source and Panacos. The Consultant shall assume an advisory role in directing the Company's PCT and Source Divisions and the Company's ownership interest in Panacos. The heads of the Company's PCT and Source Divisions shall report to the Consultant.

6. PCT Division. In performing his PCT duties set forth in Paragraph 5 above, until such time as the business plan, including the operating budget, is approved by the Board, the Consultant shall limit the monthly losses from the PCT Division to an amount equal to or less than the average monthly amount of losses that have been incurred by the PCT Division since January 1, 2003. For this purpose, however, the Consultant's salary and related expenses will not be considered in the calculation of PCT's losses. The Consultant further understands and agrees that the President of the Company, representing the Board, may determine based on the Company's overall financial condition that it may be necessary to further limit the amount of losses incurred by the PCT Division.

   Without limiting the foregoing, the Consultant shall prepare a marketing plan for the PCT Division for the Board. The marketing plan shall be prepared within a time period specified by the Board of Directors. The strategy and activities contained in the marketing plan shall include, but not be limited to, ongoing scientific review and attendance at scientific conferences, communication with leading scientific investigators in the field and investigation of potential opportunities with the United States government relating to homeland defense.

7. In performing his Source Division duties as set forth in Paragraph 5, above, but without limitation of such duties, the Consultant shall assist in identifying potential contract procurement opportunities for the Source Division and in identifying strategic opportunities for the Source Division.

8. Payment of the Commerce Loan. With the proceeds (net of required taxes) Consultant may receive from the sale of any personal assets, the Consultant shall promptly apply all such net proceeds to repay all amounts due to Commerce Bank & Trust Company ("Commerce Bank"), whether owed personally or by any affiliate of the Consultant, including Resort Accommodations International LLC ("RAI") and whether or not then due pursuant to the terms of any note or loan agreement with Commerce Bank (the "Commerce Bank Loan") and all amounts owed to the Company by the Consultant or any such affiliate pursuant to (i) that certain Limited Guaranty by the Company for the benefit of Commerce Bank dated January 15, 2002, (ii) that certain Junior Participation Agreement also dated January 15, 2002 by and between Commerce Bank, RAI and the Company, (iii) that certain Pledge Agreement also dated

January 15, 2002 by and between the Company and Commerce Bank, and (iv) that certain Pledge and Security Agreement dated as of January 15, 2002 by and between the Consultant, the Company and Commerce Bank. By entering into this Agreement, the Consultant hereby ratifies, confirms and

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acknowledges his obligations to the Company under such agreements referred to in clauses (i) through (iv) above (the "Company's Guarantee"). Notwithstanding the foregoing, if and to the extent the Consultant or his affiliates has funds or assets in excess of ordinary and routine living expenses, the Consultant shall repay the Commerce Bank Loan and the Company's Guarantee.

9. Expenses. During the term of this Agreement, the Consultant shall obtain prior approval for any and all out-of-pocket expenses incurred in connection with the performance of his duties hereunder and otherwise in accordance with the Company's reimbursement policy and procedure as in effect from time to time. If approved in advance, the Consultant shall submit invoices for such approved expenses in accordance with the Company's expense reimbursement procedures, and the Company shall reimburse him for all such approved out-of-pocket expenses.

10. Written Reports. The Company may request that plans, progress reports and results reports be provided by the Consultant on a weekly or monthly basis as requested by the Company. The reports shall be in such form and setting forth such information and data as is reasonably requested by the Company.

11. Inventions. Any and all inventions, discoveries, developments and innovations conceived by the Consultant during this engagement relative to the duties under this Agreement shall be the exclusive property of the Company; and the Consultant hereby assigns all right, title, and interest in the same to the Company. Any and all inventions, discoveries, developments and innovations conceived by the Consultant prior to his engagement hereunder and utilized by him in rendering duties to the Company are hereby licensed to the Company for use in its operations and for an infinite duration. This license is non-exclusive, and may be assigned without the Consultant's prior written approval by the Company to a wholly-owned subsidiary of the Company.

12. Confidentiality. The Consultant acknowledges that during his engagement hereunder, he will have access to and become acquainted with various trade secrets, inventions, innovations, processes, information, records and specifications owned or licensed by the Company and/or used by the Company in connection with the operation of its business including, without limitation, the Company's business and product processes, methods, customer lists, accounts and procedures. The Consultant agrees that he will not disclose any of the aforesaid, directly or indirectly, or use any of them in any manner, either during his engagement hereunder or at any time thereafter, except as required in the course of his engagement by the Company. All files, records, documents, blueprints, specifications, information, letters, notes, media lists, original artwork/creative, notebooks, and similar items relating to the business of the Company whether prepared by the Consultant or otherwise coming into his possession during his engagement hereunder, shall remain the exclusive property of the Company. The Consultant shall not retain any copies of the foregoing without the Company's prior written permission. Upon the termination of his engagement hereunder, or whenever requested by the Company, the Consultant shall immediately deliver to the Company all such files, records, documents, specifications, information, and other items in his possession or under his control.

13. Disclosure. The Consultant shall not disclose the terms of this Agreement to any person without the prior written consent of the Company. The Company may issue a

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press release to announce the Consultant's continued engagement. If the Company determines to issue such a press release, it shall promptly submit the press release to the Consultant for his review and approval prior to release to the public.

14. Conflicts of Interest; Non-hire Provision. The Consultant represents that he is free to enter into this Agreement, and that this engagement does not violate the terms of any agreement between the Consultant and any third party. Further, the Consultant, in rendering his duties shall not utilize any invention, discovery, development, improvement, innovation, or trade secret in which he does not have a proprietary interest. If the Company is not in breach of its obligations under this Agreement, for a period of one year following termination of his engagement hereunder, the Consultant shall not, directly or indirectly hire, solicit, or encourage to leave the Company's employment, any employee, consultant, or contractor of the Company or hire any such employee, consultant, or contractor who has left the Company's employment or contractual engagement within one year of such employment or engagement, (other than such employees, consultants and contractors who have been involuntarily terminated by the Company).

15. Right to Injunction. The parties hereto acknowledge that the services to be rendered by the Consultant under this Agreement, the rights and privileges granted to the Company under the Agreement, the benefits to be received by the Consultant and the obligations of the Company hereunder are of a special, unique, unusual, and extraordinary character which gives them a peculiar value, the loss of which cannot be reasonably or adequately compensated by damages in any action at law, and the breach by either party of any of the provisions of this Agreement will cause the other irreparable injury and damage. The parties expressly agree that each party shall be entitled to injunctive and other equitable relief in the event of, or to prevent, a breach of any provision of this Agreement by the other party. Resort to such equitable relief, however, shall not be construed to be a waiver of any other rights or remedies that such party may have for damages or otherwise. The various rights and remedies of the parties under this Agreement or otherwise shall be construed to be cumulative, and no one of the them shall be exclusive of any other or of any right or remedy allowed by law.

16. Termination. The Consultant's engagement hereunder may be terminated prior to December 31, 2004 as follows:

    (i) With Cause. The Board may terminate the Consultant's engagement hereunder at any time and without further obligation for cause. If the Board terminates the engagement for cause, then it shall only owe the Consultant

compensation that has accrued and has not yet been paid as of the date of termination (calculated on a daily basis). For purposes of this Agreement, "cause" shall mean the occurrence of any of the following events:

(A) any material act of personal dishonesty, or serious misconduct in connection with the Consultant's responsibilities to the Company under this Agreement;

(B) the commission by the Consultant of any crime classified as a felony under any Federal, state or local law or the Consultant engaging in any acts of moral turpitude;

(C) continued material violations, breach or noncompliance by the Consultant of the Consultant's obligations or covenants under this Agreement after there has been delivered to the Consultant a written demand for performance or compliance from the Company which describes the basis for the Company's belief that the Consultant has violated, breached or failed to comply with the Consultant's duties or complied with the Consultant's obligations or covenants under this Agreement and such violations, breach or noncompliance have not been corrected or cured by the Consultant within ten (10) business days following such demand;

(D) continued failure or refusal to comply with the written policies or reasonable directives of the Company after there has been delivered to the Consultant a written demand for performance or compliance from the Company which describes the basis for the Company's belief that the Consultant has failed or refused to comply with such policies or directives and such failure or refusal have not been corrected or cured by the Consultant within ten (10) business days following such demand; or

(E) the use by the Consultant of a controlled substance without a prescription or the abuse of alcohol which in any way impairs the Consultant's ability to carry out Consultant's duties and responsibilities under this Agreement.

17. Termination of Duties, Responsibilities and Authority. Although the Consultant's engagement hereunder shall continue through December 31, 2004, the Board may reduce, limit or terminate part or all of the Consultant's duties, responsibilities and authority to provide any services under this Agreement at any time without cause, provided however, that if the Board reduces, limits or terminates part or all of such duties, responsibilities and authority without cause prior to December 31, 2004, it shall continue to pay the Consultant all of the compensation, including benefits, which otherwise would have been paid through December 31, 2004 had the Board not so terminated such duties, responsibilities and authority. In such event, the Consultant shall continue to be referred to as the Company's Executive Project Consultant.

18. Taxes. The Company shall withhold taxes with respect to the Consultant's compensation hereunder.

19. Release. In consideration of the Company engaging the Consultant as a consultant hereunder, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Consultant hereby releases, remises, and

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forever discharges the Company and the Company's officers, directors and affiliates from all debts, demands, actions, causes of actions, suits, accounts, covenants, contracts, agreements, damages, and all claims and liabilities of every nature, which the Consultant or the Consultant's successors or assigns now have or ever had against the Company or its officers, directors and affiliates, jointly, severally, or individually.

20. Successors and Assigns. All of the provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, if any, successors, and assigns, provided, however, the Consultant shall not assign any of his rights under this Agreement, or delegate the performance of any of his duties hereunder, without the prior written consent of the Company.

21. Choice of Law. The laws of the Commonwealth of Massachusetts shall govern the validity of this Agreement, the construction of its terms and the interpretation of the rights and duties of the parties hereto.

22. Arbitration. Any controversies arising out of the terms of this Agreement or its interpretation shall be settled in Massachusetts in accordance with the rules of the American Arbitration Association, and the judgment upon award may be entered in any court having jurisdiction thereof.

23. Headings. Section headings are not to be considered a part of this Agreement and are not intended to be a full and accurate description of the contents hereof.

24. Waiver. No failure or delay by either part in exercising any right under this Agreement will operate as a waiver of such right or any other right under this Agreement. Waiver by one party hereto of breach of any provision of this Agreement by the other shall not operate or be construed as a continuing waiver.

25. Notices. Any and all notices, demands, or other communications required or desired to be given hereunder by any party shall be in writing and shall be validly given or made to another party if personally served, or if deposited in the United States mail, certified or registered, postage prepaid, return receipt requested. If such notice or demand is served personally, notice shall be deemed constructively made at the time of such personal service. If such notice, demand or other communication is given by mail, such notice

shall be conclusively deemed given five days after deposit thereof in the United States mail addressed to the party to whom such notice, demand or other communication is to be given as follows:

If to the Consultant:

Richard T. Schumacher
65 Black Pond Lane
Taunton, MA 02780

If to the Company:

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

Attn: Chairman of the Board

Any party hereto may change its address for purposes of this paragraph by written notice given in the manner provided above.

26. Modification or Amendment. No amendment, change or modification of this Agreement shall be valid unless in writing signed by the parties hereto.

27. Entire Understanding. This document and any exhibit attached constitute the entire understanding and agreement of the parties, and any and all prior agreements, understandings, and representations whether written or oral are hereby terminated and canceled in their entirety and are of no further force and effect.

28. Unenforceability of Provisions. If any provision of this Agreement, or any portion thereof, is held to be invalid and unenforceable, then the remainder of this Agreement shall nevertheless remain in full force and effect.

29. Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

30. Captions. Captions have been inserted solely for the convenience of reference and in no way define, limit or describe the scope or substance of any provisions of this Agreement.

IN WITNESS WHEREOF the undersigned have executed this Agreement as of the day and year first written above. The parties hereto agree that facsimile signatures shall be as effective as if originals.

Boston Biomedica Inc.

By: /s/ R. Wayne Fritzsche
Its: Chairman of the Board

Consultant:

By: /s/ Richard T. Schumacher
Richard T. Schumacher

Exhibit 10.32

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING

2. CONTRACT (Proc. Inst Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION PURCHASE REQUEST/PROJECT NO.
N02-CP-11001	**06/01/2001**	

5. ISSUED BY CODE **261011001**

National Cancer Institute
Research Contracts Branch, ESS
Executive Plaza South, Room 620
9000 Rockville Pike MSC 7224
Bethesda Maryland 20892-7224

6. ADMINISTERED BY (If other than item 5) CODE

OD
Office of Director
Division of Epidemiology and Genetics
(RFP No. N02CP11001-66)

7. NAME AND ADDRESS OF THE CONTRACTOR (No., street, city, county, State and ZIP Code)

BBI Biotech Research Laboratories
217 Perry Parkway
Gaithersburg, Maryland 20877

8. DELIVERY

☒ FOB Destination ☐ FOB Origin

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (a copies unless otherwise specified) TO THE ADDRESS SHOWN IN ITEM SEE SECTION G ARTICLE G. 4.

PLACE OF PERFORMANCE: **Frederick, Maryland**

CODE FACILITY CODE u

11. SHIP TO/MARK FOR CODE

SEE SECTION F, ARTICLE F.1.

12. PAYMENT WILL BE MADE BY CODE

SEE SECTION G, ARTICLE G.4.

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION

10.U.S.C. 2304(c) ( ) ?1 U.S.C. 253(c) ( )

14. ACCOUNTING AND APPROPRIATION DATA

CAN1	**18332860**	TIN	**043152484**
CAN2		DOC NO.	**N2CP11001A**
OC CODE	**25.2E**	LOC	

15A. ITEM NO.	15B SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
TITLE:	**Laboratory Support for Processing and Storage of Biological Specimens for Persons at High Risk of Cancer**			**CAN1:** **CAN2:**	**$ 1,500,000** **$**
CURRENT OBLIGATION:					**$ 1,500,000**
CONTRACT PERIOD:	**06/01/2001 through 05/31/2006**				**$**
CONTRACT TYPE:	**Cost-Plus-Fixed Fee, COMPLETION,** Work Assignments				**$**
	15G. TOTAL AMOUNT OF CONTRACT				**$ 10,326,558**

16. TABLE OF CONTENTS

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		PART I - THE SCHEDULE
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X	C	DESCRIPTION/SPECS/WORK STATEMENT
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X	I	CONTRACT CLAUSES

PART III - LIST OF DOCMENTS, EXHIBITS AND OTHER ATTACH

X	J	LIST OF ATTACHMENTS

PART IV - REPRESENTATIONS AND INSTRUCTIONS

X	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS
	L	INSTRS.. CONDS.. AND NOTICES TO OFFERORS
	M	EVALUATION FOR AWARD

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTORS NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. ☐ AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number including the additions or changes made by you which additions or changes are set forth in full above, is herein accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER (Type or print)
Mark Manak, General Manager

20A. NAME OF CONTRACTING OFFICER
SHARON A. MILLER

19B. NAME OF CONTRACTOR
BY /s/ Mark Manak
(Signature of person authorized to sign)

19C. DATE SIGNED
May 8, 2001

20B. UNITED STATES OF AMERICA
BY /s/ Sharon A. Miller
(Signature of Contracting officer)

20C. DATE SIGNED
6-1-01

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STANDARD FORM 26 (REV 4-85)
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DETAILED TABLE OF CONTRACT CONTENTS

SECTION B - - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective of this acquisition are to support molecular epidemiology projects undertaken by the Division of Cancer Epidemiology and Genetics. National Cancer Institute. These technical services shall include:

- Accessioning and processing biological specimens for molecular epidemiology studies
- Organizing, aliquoting and dispersing samples to DCEG collaborators
- Maintaining the existing blorepository and expanding it as necessary
- Maintaining accurate information on the quality, quantity and location of samples, and to provide these data in a timely manner for the computerized sample inventory
- Exploring new or improved methods to achieve the above objectives in a more cost-efficient manner
- Conducting method studies as required to resolve issues of direct relevance to specimen processing or storage
- Evaluating and piloting new technologies germane to the contract mission
- Maintaining appropriate quality assurance systems for the biorepository and bioprocessing laboratories.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $9,811,557.

b. The fixed fee for this contract is $515,001. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The Government's obligation, represented by the sum of the estimated cost plus fixed fee, is $10,326,558.

d. Total funds currently available for payment and allotted to this contract are $1,500,000 of which $1,426,262 represents the estimated costs, and of which $73,738 represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through February 28, 2002.

f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses, ALLOWABLE COST AND PAYMENT, and FIXED FEE, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

(1) Acquisition, by purchase or less, of any interest in real property;

(2) Special rearrangement or alteration of facilities;

(3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than

research, such as office equipment and furnishings, pocket calculators, etc.);

(4) Travel to attend general scientific meetings;

(5) Foreign travel - See b (2) below:

(6) Consultant costs

(7) Subcontracts;

(8) Patient care costs;

(9) Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide for Control of Government Property), 1990, regardless acquisition value.

b. **Travel Costs**

(1) Domestic Travel

(a) Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed $4,885 without the prior written approval of the Contracting Officer.

(b) The Contractor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.205-46.

(2) Foreign Travel

Requests for foreign travel must be submitted at least six weeks in advance and shall contain the following: (a) meeting(s) and place(s) to be visited, with costs and dates; (b) name(s) and title(s) of Contractor personnel to travel and their functions in the contract project; (c) contract purposes to be served by the travel; (d) how travel of contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of NIH contract funds; (e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and (f) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without

further authorization from the Contracting Officer.

a. Total expenditures for moving freezers to 5107 Pegasus Court, Frederick, MD from 217 Perry Parkway, Gaithersburg, MD incurred in direct performance of this contract shall not exceed $83,040 without prior written approval of the Contracting Officer.

b. The government's obligation under this contract is the total dollars authorized by the work assignments issued under the contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, SECTION J, ATTACHMENT I, dated August 2000, attached hereto and made a part of this contract.

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract:

(1) Quarterly Computerized and Written Reports

The Contractor shall submit Quarterly Computerized and Written Reports summarizing the status of all newly received specimens and outlining all dispersals by the laboratory. The information should by tracked by project code and submitted with the quarterly report. A summary of all correspondence consisting of requests for shipment, cover letters and inquiries from outside collaborators shall be submitted quarterly to the NCI Project Officer and made available upon request. Emphasis shall be on conciseness as well as comprehensiveness.

The first quarterly report shall cover the period consisting of the first full calendar quarter following the effective date of the contract and shall be due on or before September 15, 2001. Thereafter, reports shall be due on or before the 15th day of the month following each quarterly reporting period. A Quarterly Computerized and Written Report shall not be required when submitting the Annual Reports or Final Report.

(2) Annual Technical Progress Report

The Contractor shall prepare Annual Technical Progress Reports which explain the progress of work performed under this contract. Each report shall describe the progress of the project to date, nothing all technical areas in which effort is being directed and indicating the status of work in each area. This report shall include:

a) A quantitative summary of the number of specimens processed by the Contractor, their type and investigator source;

b) Shipments and logistics;

c) An indication of current problems that may impede performance under the contract and proposed corrective action; and

e) A summary of work assignments issued to date, general progress on each work assignment, and the estimated and actual cost to date on each assignment.

d) A discussion of work to be performed during the next reporting period.

The annual report shall, in addition, include the information described in item #9 of the statement of work. Additional interim reports may be requested as necessary.

The first annual report shall cover the period consisting of the first full calendar year following the effective date of

the contract and shall be due on or before July 1, 2002. Emphasis shall be on conciseness as well as comprehensiveness. A separate annual technical progress report shall not be required when submitting the Final Report.

(3) Final Technical Progress Report

The Contractor shall submit a final technical progress report on or before the expiration date of the contract. The Final Report shall include information in sufficient detail to describe comprehensively the results achieved and shall include a summation of the work performed for the entire period of performance.

SECTION D - PACKAGING, MARKING AND SHIPPING

ARTICLE D.1. PACKAGING

Specimens shall be protected from temperature extremes by use of insulated containers or other acceptable means as needed. Portable liquid nitrogen containers for transport of frozen cells shall also be required.

ARTICLE D.2. MARKING

All deliverable under this contract shall be clearly identified with the subject contract number. All specimens shall be submitted to the Contractor, accompanied by written identification of the specimen source, using forms supplied by the Project Officer. All specimens will be submitted to the Contractor with a unique alpha-numeric code number which will be the only identification of the specimen in future laboratory processing, dispersal, etc. The name of the donor shall not be used in the labeling of specimens by laboratory personnel. **No names of persons enrolled in AIDS-associated studies shall be written on vials.**

ARTICLE D.3. SHIPPING

The Contractor shall prepare specimens for shipment, supply shipping containers appropriate to maintain specimens in the proper state (cool, frozen, deep frozen, etc.) and make arrangements through commercial air freight companies and other carriers to send biologic specimens to collaborating investigators in an expeditious (e.g. overnight or same day) fashion. For immunologic or genetic typing studies, for example, the Contractor shall prepare specimens for delivery to the local Human Leukocyte Antigen (HLA) typing laboratory or immune function laboratory in a suitable form. The local in-house delivery service shall be used for these particular specimens to ensure expeditious delivery under optimum conditions. In some cases, commercial freight companies shall be used for overnight shipments to investigators in other cities. The Contractor shall be responsible for notifying the receiving laboratory of the specimens shipment and anticipated arrival time to insure that the receiving laboratory is prepared to receive the specimens.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Project Officer identified in ARTICLE G 1 is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at the National Cancer Institute, 6120 Executive Boulevard. Room 7020. Bethesda. MD 20892.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized

representative within 60 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause No. 52.246-5, INSPECTION OF SERVICES-COST REIMBURSEMENT (APRIL 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in SECTION C, ARTICLE C.2. will be required to be delivered F.O.B. Destination as ser forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract:

Item	Description	Quantity	Delivery Schedule
(1)	Quarterly Computerized and Written Reports	3	First report due 09/15/01; all others due on the 15th day of the month following each Quarterly reporting period.

(2)	Annual Technical Progress Report	3	July 1, 2002 July 1, 2003 July 1, 2004 July 1, 2005
(3)	Final Technical Progress Report	3	On or before May 31, 2006

b. The above items (1) through (3) shall be addressed and delivered to:

Original: Contracting Officer
Epidemiology and Support Section
Research Contract Branch, OD
National Cancer Institute
Executive Plaza South, Room 620
6120 EXECUTIVE BLVD MSC 7224
BETHESDA, MD 20892-7224

Copies: Project Officer
Office of the Director
Division of Cancer Epidemiology & Genetics
Executive Plaza South, Room 7020
6120 EXECUTIVE BLVD MSC 7242
BETHESDA, MD 20892-7242

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15. Stop Work Order (AUGUST 1989) with ALTERNATE (APRIL 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer and Assistant Officers will represent the Government for the purpose of this contract:

Dr. Jim Vaught, Project Officer

Assistant Project Officers: Dr. Dalsu Baris
Dr. Mark Green
Dr. Rashmi Sinha
Dr. Mark Schiffman
Dr. Charles Rabkin
Dr. Neil Caporaso

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Assistant Project Officer's will be responsible for coordinating the requirements of their individual DCEG Branch. Assistant Project Officer's will not be allowed to initiate Work Assignments for contract support or to modify ongoing contract tasks without discussing with the Project Officer.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in this contract, the following individuals are considered to be essential to the work

being performed hereunder:

Name	Title
Mark Cosentino	**Principal Investigator**
Jay Ji	**Assistant Investigator**
Andy Slywester	**Assistant Investigator**
Kathi Shea	**Assistant Investigator**
Caria Hanson	**Project Manager**

ARTICLE G.3. WORK ASSIGNMENT PROCEDURES

In providing support under this contract, the Contractor shall initiate work only when so directed by a Work Assignment (Attachment provided in SECTION J). Approval of a Work Assignment shall not constitute approval to exceed any item listed in the contract or general clauses of the contract. Work Assignment amounts shall not exceed the total amounts listed in the contract (time, dollars, consultants, travel, etc.). The Project Officer with Contracting Officer approval, is authorized to initiate Work Assignments and to sign Work Assignments indicating satisfactory performance/delivery of the services/product required in each work Assignment. The Contractor shall assure, prior to commencing work on any Work Assignment, that written approval of the Project Officer and the Contracting Officer has been obtained. A Work Assignment which does not contain both Contracting Officer and Project Officer approval signatures shall be considered invalid and costs incurred for such work shall be considered unallowable. The Contractor shall not exceed the estimated Work Assignment amount, or change the Work Assignment leader without prior written approval of the Project Officer and the Contracting Officer by modification of the Work Assignment. The day-to-day operational and administrative details of the Work Assignment system will be established by the Project Officer with input from the Contractor. The work assignment system will operate within the following general guidelines:

a. Work Assignment (W.A.) Information

(1) All work to be assigned under this contract shall relate directly to one or more of the work areas listed in the Statement of Work.

(2) Each W.A. shall be written for the conduct of specific, finite task.

(3) Each new W.A. shall be numbered serially beginning with 01.

(4) Each W.A. shall be completed on form entitled “NCI Contract Work Assignment” and listed as an Attachment in Section J of this contract.

(5) Upon award of the contract, an Administrative Work Assignment as shown in SECTION J, Attachments, shall be issued on a yearly basis. This Work Assignment will cover the expenditures necessary for the administration of the contract.

b. Initiation of a W.A.

(1) The Project Officer will initiate Part I of the W.A.

(2) The Contractor shall complete Part II and obtain the appropriate signature. The Contractor shall forward the proposed W.A. to the Project Officer.

(3) Upon receipt of the proposed W.A. and after determining that the proposed W.A. is acceptable, the Project Officer will sign Part II to indicate recommendation for approval and forward to the Contracting Officer.

(4) Upon receipt the Contracting Officer will review the proposed W.A.

(a) If approved, the Contracting Officer will sign Part II to indicate approval and will forward the W.A. to the Contractor with a copy to the Project Officer.

(b) If not approved, the Contracting Officer will notify the Project Officer, stating the reasons for disapproval.

(5) After receipt of the approved W.A., the Contractor shall begin work. The period of performance shall never precede the Contracting Officer approval date.

c. Modification to a W.A.

(1) Each amendment to an existing Work Assignment shall contain the original W.A. number and shall designate a modification number. Modification numbers for each W.A. shall be serially numbered beginning with 01 (for example, Work Assignment 01, Modification No. 01).

(2) Each W.A. Modification shall set forth in specific detail which portion(s) of the W.A. is to be modified. All Cost/Labor modifications shall be in the following format:

	Authorized to Date	This Modification	Revised Estimate
Cost Elements (List Each Element)			

d. Conclusion of a W.A.

(1) For each W.A. performed, the Contractor shall prepare PART III of the Work Assignment for submission to the Contracting Officer.

(2) This PART III submission shall include all actual information (cost, and deliverables) relative to the W.A.

(3) PART III of the W.A. shall be submitted as soon as possible and not to exceed three months after the closing date of the W.A. For those work assignments which expire within three months prior to the contract expiration date. PART III of the Work Assignment shall be submitted on the final contract day.

(4) After verification that all work is complete and deliverables have been received and accepted, the Project Officer will sign part III of the W.A. to indicate recommendation for approval and forward the W.A. to the Contracting Officer.

(5) After verification that the W.A. has been satisfactorily completed, the Contracting Officer will approve completion of the W.A. by signing Part III of the W.A. and forward to the Contractor.

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-I are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

(1) Invoices/financing requests shall be submitted as follows:

An original and two copies to the following designed billing office:

Contracting Officer
Research Contracts Branch
National Cancer Institute, NIH
EPS, Room 620
6120 EXECUTIVE BLVD MSC 7224
BETHESDA MD 20892-7224

(2) Inquiries regarding payment of invoices should be directed to the designed billing office, (301)496-8611.

(3) Inquiries regarding actual payment of invoices should be direct to the designed payment office, (301)496-6452.

b. Each invoice shall include a summary of costs incurred on each work assignment. The total costs incurred on all work assignments for the month shall match the total amount billed on the invoice.

c. Fee billed under this contract shall be based upon total costs excluding equipment costs.

ARTICLE G.5. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of costs (expenditure categories) which shall be reported within the total contract are discussed in paragraphe., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise started in that part of the Instructions for Completing Form NIH 2706, entitled "**PREPARATION INSTRUCTIONS**," all columns A through J, shall be completed for each report submitted.

c. The first financial reports shall cover the period consisting of the FIRST FULL THREE CALENDAR MONTHS following the date of the contract in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated within the Financial Report of Individual Project/Contract, NIH

2706, SECTION J, ATTACHMENT 4, attached hereto and made a part of this contract.

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

ARTICLE G.6. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d) (2), Allowable Cost and Payment incorporated by reference in this contract in Part II, section I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Officer of Contracts Management
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC-7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLES G.7. GOVERNMENT PROPERTY

a. In additional to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of DHHS Publication, **Contractor's Guide for Control of Government Property, 1990**, which is incorporated into this contract by reference. Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract. A copy of this publication is available upon request to the Contracts Property Administrator.

This contract's Contracts Property Administrator is:

Contracts Property Administrator
Division of Personal Property Services, NIH
6011 Building, Suite 637
6011 EXECUTIVE BLVE MSC 7670
BETHESDA MD 20852-7670
(301) 496-6466

b. Notwithstanding the provisions outlined in the DHHS Publication. **Contractor's Guide for Control of Government Property**, 1990 which is incorporated in this contract in paragraph a. above, the contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for performing annual inventories required under this contract. This form is included as an attachment in SECTION J of this contract.

c. Contractor-Acquired Under Government Property - Schedule I-B

Pursuant to the clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor will be authorized to acquire the property listed in the attached Schedule I-B for use in direct performance of the contract, following receipt of the Contracting Officers written approval, based on contractor-furnished prices and evidence of competition.

d. Property Acquired under Predecessor Contract - Schedule II-A

Pursuant to the clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contract is hereby authorized to retain custody of all Government Property acquired or furnished under predecessor Contract No. N02-CP-71001 for use in direct performance of this contract. Accountability for the items is hereby authorized to be transferred to this contract from the predecessor contract. Upon completion of each contract, the contractor agrees to furnish to the Contracting Officer, without delay, the inventory schedule covering all Government Property furnished or acquired for use in the performance of the predecessor contract as provided by the clause, GOVERNMENT PROPERTY, of that contract and the instructions contained in DHHS Publication entitled, Contractor's Guide for control of Government Property, (1990).

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. Any disagreement between the parties regarding an evaluation will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:
http://ocm.od.nih.gov/cdmp/cps contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will

be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLES H.1. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant office for review. Since these projects may be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

ARTICLE H.2. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contactor for use by anyone other that the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.3. HUMAN MATERIALS

It is understood that the acquisition and supply of all human specimen material (including fetal material) used under this contract will be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.4. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) citied in paragraph b., below contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 106-554, Section 505	2001	(10/1/00 - 9/30/01)

ARTICLE H.5. PRIVACY ACT

This procurement action requires the Contractor to do one more of the following; design, develop, or operate a system of

records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penaltics.

The Privacy Act System of Records applicable to this projects is Number 09-25-0200. This document is incorporated into this contract as Attachment 6.

ARTICLE H.6. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR Clause 352.224-70, Confidentiality of Information (APRIL 1984):

- Identification of Specimen source or donor name;
- All records of manipulations on all sepecimens;
- Information concerning the identification of the patient, the diagnosis, demographic information or other such information;
- Written, hard-copy records of inventory sheets.

ARTICLE H.7. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, under Contractor No. N02-CP-11001."

ARTICLES H.8. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the projects or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b.

Public Law and Section No.	Fiscal year	Period covered
P.L. 106-554, Section 505	2001	(10/1/00-9/30/01)

ARTICLE H.9. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is;

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on (http://www3.od.nih.gov/oma/mantial/chapters/management/1754/)

PART II - CONTRACT CLAUSES

SECTION I - - CONTRACT CLAUSES

ARTICLE 1.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)

52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes

52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Mar 2000	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Oct 2000	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	Jan 1997	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)

52.227-3	Apr 1984	Patent Indemnity
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jun 1997	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer—Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs

52.242-3	Oct 1995	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate I (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.246-25	Feb 1997	Limitation of Liability - Services (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT - Rev. 2/2001].

ARTICLE 1.2 AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE 1.1. of this SECTION is hereby modified as follows:

FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (OCTOBER 2000), and FAR Clause 52.219-16, LIQUIDATED DAMAGES—SUBCONTRACTING PLAN (JANUARY 1999) are deleted in their entirety.

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF

FUNDS (APRIL 1984) is substituted therefor. **Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.**

ARTICLE 1.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the contracting officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER ?) CLAUSES

(1) FAR 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

(2) FAR 52.219-6, Notice of Total Small Business Set-Aside (JULY 1996).

(3) FAR 52.219-14, Limitations on Subcontracting (DECEMBER 1996).

(4) FAR 52.224-1, Privacy Act Notification (APRIL 1984).

(5) FAR 52.224-2, Privacy Act (APRIL 1984).

(6) FAR 52.227-14, Rights in Data - General (JUNE 1987).

(7) FAR 52.247-63, Preference for U.S. Flag Air Carriers (JANUARY 1997).

(8) FAR 52.251-1, Government Supply Sources (APRIL 1984).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

(1) HHSAR 352.223-70, Safety and Health (JANUARY 2001).

(2) HHSAR 352.224-70, Confidentiality of Information (APRIL 1984).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

(1) NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

ARTICLE 1.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause 52.244-6, **SUBCONTRACTS FOR COMMERCIAL ITEMS AND COMMERCIAL COMPONENTS** (OCTOBER 1998)

(a) **Definition.**

Commercial item, as used in this clause, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, as used in this clause, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

(c) Notwithstanding any other clause of this contract, the Contractor is not required to include any FAR provision or clause, other than those listed below to the extent they are applicable and as may be required to establish the reasonableness of prices under Part 15, in a subcontract at any tier for commercial items or commercial components:

(1) 52.222-26, Equal Opportunity (E.O. 11246);
(2) 52.222-35, Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (38 U.S.C. 4212(a));
(3) 52.222-36, Affirmative Action for Workers with Disabilities (29 U.S.C. 793); and
(4) 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (46 U.S.C. 1241) (flow down not required for subcontracts awarded beginning May 1, 1996).

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III

SECTION J - - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, August 2000, 5 pages.
2. Sample Contract Work Assignment, 4/95, 3 pages.
3. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1 (5/97), 4 pages.
4. Financial Report of Individual Project/Contract, NIH 2706, (5/97), 1 page.
5. Instructions for Completing form NIH 2706, Financial Report of Individual Project/Contract, (5/97), 3 pages.
6. Privacy Act System of Records, Number 09-25-0200, as cited in the Federal Register Notice issued in Volume 62, Number 66, pages 16596-16602, dated 4/7/97.
7. Safety and Health, HHSAR Clause 352.223-70, (1/01), 1 page.
8. Procurement of Certain Equipment, NIH(RC)-7, 4/1/84, 1 page.
9. Government Property - Schedule I-B.
10. Government Property - Schedule II-A.
11. Report of Government Owned, Contractor Held Property, 1 page.

PART IV

SECTION K - - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. Representations and Certifications, dated November 14, 2000.

END of the SCHEDULE
(CONTRACT)

STATEMENT OF WORK

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work below:

1) The Contractor shall provide the services described below in accordance with Contractor-developed, Government-approved protocols:

a) Separation and viable cryopreservation of blood mononuclear lymphocytes;

b) Separation, aliquoting and storage of serum, plasma and/or urine as needed;

c) Cryopreservation of bone marrow samples;

d) Storage of tumor extracts;

NOTE: Tumor extracts are not synonymous with the preparation of tumor antigens. Specific protocols will be provided by the NCI for extract preparations.

e) Cryopreservation of whole tumor tissue;

NOTE: Specimens may range in size from 0.5 - 100 or more grams. Tumor tissues will be cut to specified sizes and flash frozen in liquid nitrogen. They will then be stored in vials in liquid nitrogen. Tumor lines, which have already been established, may be viably cryopreserved and stored.

f) Cryopreservation of intact red blood cells;

g) Viable cryopreservation of previously established lymphoblastoid cell lines;

h) Storage of DNA and other biological materials as specified by the Project Officer (e.g., pathology slides and tissue block);

i) Extraction of DNA from biologic materials;

j) Specimen processing as required by NCI to preserve special biologic materials;

k) Logging in, labeling and tracking of each vial of each sample employing an NCI developed computerized specimen tracking system, including all laboratory safeguards to insure the fidelity and purity of each sample.

NOTE: In one “typical” day, the most labor-intensive procedure would be the processing of whole blood for cryopreservation of leukocytes. As many as 30 samples of approximately 30 ml each could be received.

l) Maintenance of the previously-established repository currently containing more than 2.0 million biological specimens and allowance for an estimated increase of up to 100% of freezer storage space.

m) Under the direction of the Project Officer conduct laboratory methods studies that establish optimal conditions for collection, processing, shipping and storage of biologic materials.

Processing services shall be available routinely between the hours of 9:00 a.m. and 2:00 p.m., Monday through Friday and at any other time (including nights, weekends and holidays) by special arrangement, usually with advance notice. A laboratory staff member shall be available during nonbusiness hours for emergency specimen processing (as might occur when a patient dies). A biohazard area adequate for processing specimens with Acquired Immunodeficiency Syndrome (AIDS) shall be available for the processing of all biologic samples.

2) The Contractor shall supply messenger service to pick up specimens or inter-laboratory communication from medical care facilities in the Washington, D.C., area or at area transportation centers (i.e., Dulles International, D.C. National and Baltimore/Washington International Airports). This messenger service shall be supplied by the Contractor and not subcontracted to commercial carriers. All specimens submitted to the laboratory for processing shall be scheduled in advance, except in emergencies as detailed below. Specimens shall be delivered to the Contractor’s laboratory within four hours of notification for pick-up. Specimens shall be protected from temperature extremes by use of insulated containers or other acceptable means as needed. A portable liquid nitrogen container for transport of frozen cells or tumor specimens shall also be required. Only specimens provided by or approved by the Project Officer shall be accepted for processing and storage by the Contractor.

3) The Contractor shall be responsible for recording and monitoring the location of all specimens that are being sent or received through use of a logbook of all requests and specimens. The Contractor shall be responsible for monitoring, shipping and receipt of specimens to minimize delay or loss. If a specimen is not received within four hours of expected

delivery, the Contractor shall inform the Project officer by telephone. An after-hours telephone number of the Contractor's staff member shall be available to assist in this follow-up and the staff member shall be available at that number. The Contractor shall be responsible for immediately tracing the location of delinquent specimens not received when expected. All specimens that are of questionable research value shall be noted and the Project Officer notified by telephone within 24 hours, as well as in writing within 3 business days, providing identifying names or numbers, quantity, place of origin, a concise narrative description of the event, etc., so that appropriate action can be initiated. The Contractor shall designate a specific individual to be responsible for after-hours specimen processing and name an alternate to act when the primary person is not available.

4) The Contractor shall maintain a repository of biologic specimens for the NCI Division of Cancer Epidemiology and Genetics (DCEG). This repository shall include frozen serum, plasma, urine, tumor tissue, tumor tissue extracts, whole red blood cells, separated and frozen white blood cells, or fractions of white blood cell populations, bone marrow cells, body fluids, lymphoblastoid cell lines, DNA, stool specimens or smears or slides, pathology paraffin blocks, and other types of specimens as specified by the Project Officer. These materials shall be maintained at optimum temperatures for long-term storage, including liquid nitrogen, if appropriate.

5) All specimens will be submitted to the Contractor, accompanied by written identification of the specimen source, using forms supplied by the Project Officer, Specimens from members of NCI-associated families will be submitted with a unique identification number to insure compatibility with NCI laboratory computer databases. Specimens shall be assigned a unique code number, which shall be the only identification of the specimen in future laboratory processing, dispersal, etc. This code numbers shall comply with the format and convention established by the NCI Project Officer. The name of the donor shall not be used in labeling of specimens or in correspondence concerning the specimen by laboratory personnel. Such labeling shall uniquely identify each vial of each specimen and the quality of that individual vial will be recorded and updated as needed in the NCI-developed computer system.

6) The Contractor shall provide and train primary and backup staff in the operation of a computerized record

system for specimens which has been developed and furnished by the Project Officer. Using this system, the laboratory shall keep records of all manipulation on all specimens and accurately enter data on each specimen. The data shall include but not be limited to vial identification number, study ID, material type and material description, volume, weight or cell concentration, freezer location, subject ID, crisis events, data received, specimen vial quality, etc. Data shall be entered into the system, with attention to extreme accuracy, within 48 hours of receipt, or as specified by the NCI Project Officer. The Contractor shall be responsible for extracting this information from either data forms or floppy disks, which will be transmitted with the samples. The Contractor shall also use this system to monitor and track all activities related to specimens. The Project Officer will supply computer support for generating management reports for the contractor on a regular basis.

7) The Contractor shall prepare a variety of specimens for storage. Specifically, white blood cell separation, fractionation and viable cryopreservation, red blood cell cryopreservation, serum separation and storage of aliquots of 0.5 ml, plasma separation and storage, tumor tissue freezing, tumor tissue extracts, urine, serum, or blood fluid lyophilization, freezing and/or extraction of stool specimens and other techniques as required. Specimens shall be stored in containers impervious to entry of CO_2 so that they can be shipped on dry ice. Shipment of specimen in liquid nitrogen "dry shippers" may also be required. In order to ensure the viability of valuable specimens, the contractor shall be prepared to have appropriate personnel travel to a contract site, foreign or domestic, to train local staff on optimal techniques for freezing viable material.

8) Freezers shall be equipped with a stylus recording system indicating consistency of temperature, which shall be reviewed on a scheduled basis each day at specified time. Freezer malfunctions must give warning by means of an alarm system. The Contractor must provide a central alarm system monitored 24-hours a day, 365 days a year. A switch-operated electric generator of appropriate wattage for these particular freezers shall be hooked up and be maintained on standby in the event of a major power outage. Liquid nitrogen freezers must have automatic filling mechanisms drawing on a constant central source of liquid nitrogen with emergency back up. All unplanned defrostings must be logged, giving date and times during which defrostings were in effect and temperature reached, and reported to the Project Officer by telephone and in writing as described above.

9) The laboratory shall keep clear records of all manipulations on all specimens and carefully document specimen type, volume, cell concentration, source, "crisis events", etc. for each sample. The exact freezer location shall be known for each specimen and shall be kept in a master log that is easy to understand. Information shall be supplied routinely to the NCI Project Officer on forms designed and supplied by NCI in conjunction with laboratory personnel. These records shall include number of vials, exact location of vials and specimen type. The Contractor shall conduct an inventory totaling 20 percent of all stored specimens on an annual basis and include the results in the Annual Report. The annual inventory shall be conducted in a manner that results in a complete inventory of all stored specimens over the course of the contract. Thorough quality control protocols must be designed, documented and approved by the NCI Project Officer. These protocols must be rigorously implemented in the conduct of the inventories. The results of each inventory shall be documented in the annual Technical Progress Report.

10) The Contractor shall respond only to written (electronic mail will acceptable) requests for biological specimens from collaborating investigators, which have been approved by the NCI Project Officer or his/her designee(s). Specimens shall

not be sent to any investigator without a written request from the NCI Project Officer or his/her designee(s). A copy of this written request and Contractor-generated correspondence shall be sent to the NCI Project Officer. All written requests for specimen distribution shall be acted upon within four working days of receipt, unless permission to delay such action is obtained from the Project Officer.

The Contractor shall not supply the outside collaborator with any information concerning the biological specimens other than code number, specimen type or other information essential to specimen processing.

Requests for identification of the patient, the diagnosis, demographic data or other such information shall be referred to the NCI Project Officer.

The Contraction shall **NEVER** send out the last vial from a particular specimen without explicit authorization from the Project Officer.

11) The Contractor shall prepare specimens for shipment, supply shipping containers appropriate to maintain specimens in the proper state (cool, frozen, deep frozen, etc.) and make arrangements through commercial air freight companies and other carriers to send biologic specimens to collaborating investigators in an expeditious (e.g., overnight or same day) fashion. For immunologic or genetic typing studies, for example, the Contractor shall prepare specimens for delivery to the local HLA typing laboratory or immune function laboratory in a suitable form. The local in-house delivery service shall be used for these particular specimens to ensure expeditious delivery under optimum conditions. In some cases, commercial freight companies shall be used in overnight shipments to investigators in other cities. The Contractor shall be responsible for notifying the receiving laboratory of the specimens' shipment and anticipated arrival time to insure that the receiving laboratory is prepared to receive the specimens. All specimens for both immunologic testing and HLA typing and serum or other type storage shall be processed by the Contractor. Peripheral blood cells shall be aliquotted for storage in suitable quantities for subsequent testing. Other specimens, such as red blood cells, plasma, serum, urine, stool, tumor tissue, and body fluids shall be processed for storage in appropriate aliquots.

12) A large repository of sera and cells used for immunogenetic tissue typing shall be inventoried, stored and maintained under this contract. This shall include preparing appropriate inventory forms for specimen storage, retrieval and shipment.

The laboratory shall retain written, hard copy records of inventory sheets and shall supply copies in suitable form for computer entry by NCI computer support personnel. Laboratory personnel shall verify the accuracy of information as it is entered in the computer against the original data, and errors shall be corrected.

13) The Contractor shall be prepared to process the following quantities of materials:

Material	Max Daily (vials)	Typical Total Monthly Volume (Individual Sample vials)
WBC Cryopreservation	60	250
Plasma/serum aliquoting	60	250
RBC cryopreservation	25	750
Pelleted lymphocytes	15	600
Buffy coat preps	20	300
Receipt frozen vials	10,000	17,000
Thawing/ aliquotting	N/A	500
Dispersal of specimens	N/A	10,000
DNA purification	N/A	400

Although these are **ESTIMATES** of the amount of work, the Contractor must be able to accommodate highly variable amounts of processing and possible changes in specimen types and volumes depending on the new studies evolving during the contract (e.g. increased processing of buccal swabs and rinses; gastric juice; feces; urine, etc.). All prioritization of the specimen processing is determined by the NCI Project Officer. Not all maximal quantities of each material will arrive on a given day.

For this aspect of the contract, it is anticipated that technicians shall be available at least one day per weekend through the entire period of this contract (the weekend blood samples will be less than 200 ml and from less than five donors).

14) The Contractor shall handle international shipments of biological specimens (blood components, urine, gastric juice, and biopsy specimens) and clearance of these shipments through U.S. and foreign customs. The Contractor must provide a separate shipping/customs agent to coordinate shipping, clear specimens through customs at U.S. entry port, transfer to appropriate courier/express delivery service for shipment within the U.S., and notify Contractor of all arrangements so that specimens can be easily tracked. Close coordination is vital because these samples may need to be kept frozen with dry ice, and freezer-to-freezer shipping time must be less than 72 hours. Delays of just one or two days will seriously jeopardize months of scientific and medical work. Large quantities of samples are shipped from Europe, the East Indies, Africa, China

and other geographic locales. In each instance, the repository Contractor shall have responsibility for coordinating logistics to insure their timely arrival, including contracting with appropriate customs brokers and agents to expedite shipment and customs clearances.

15) The Contractor, with input from the Project Officer, shall develop methods and procedures that improve the quality and efficiency of current biologic specimen collection, processing, shipping or storage protocols. Examples of such studies are: Specimen stability with respect to various storage conditions and analyses; nucleic acid extraction methodology; comparison of serum and plasma in serologic assays; evaluation of specimen shipping protocols; evaluation of processing/aliquoting for chip-based approaches; evaluation of suitable method to preserve RNA, especially mRNA.

CONTRACT WORK ASSIGNMENT (W.A.)

Contractor: BBI - Biotech Research Laboratories
Dr. Mark Cosentino
5107 Pegasus Court
Frederick, MD 21704

W.A. Title:

Contract No: N02-CP-11001

W.A. No: Modification No.:

W.A. Originator:

Contracted Task Area:

Date Prepared:

Part I. INITIATOR'S REQUEST

A. Period of Performance: From to
B. Task Description

C. Task Leader

D. Deliverables

E.W.A. Response Due Date:

Contract Work Assignment
April, 1995

ATTACHMENT 2

CONTRACT WORK ASSIGNMENT (W.A.)

Contractor: BBI - Biotech Research Laboratories
Dr. Mark Cosentino
5107 Pegasus Court
Frederick, MD 21704

Contract No: N02-CP-11001

W.A. No: Modification No: Date Prepared:

Part II. CONTRACTOR'S RESPONSE TO W.A. REQUEST
(The Contractor may attach additional sheets to this form to present requested data.)

A. Estimated Cost and Effort

1. Labor hours - list W.A. leader, specific individuals to be assigned, labor category, and estimated hours for each.
2. Labor costs - list by labor category and total.
3. Employee benefits.
4. Direct materials
5. Travel
6. Subcontracts
7. Other direct costs
8. Indirect costs
9. Total estimated costs for this Order
10. Fee
11. Equipment
12. Total Estimated Cost and Fee

B. Detailed description of the approach to be used and of the deliverable(s). (Be specific.)

APPROVAL TO PROCEED: The Contractor shall not exceed the estimated W.A. amount, or change the W.A. leader without the prior written approval of the Project Officer and the Contracting Officer.

1. For the Contractor: _____ Date: _____
(Signature)

Typed name: _____

2. For the Government: _____ Date: _____
(Project Officer)

_____ Date: _____
(Contracting Officer)

CONTRACT WORK ASSIGNMENT (W.A.)

Contractor: BBI - Biotech Research Laboratories
Dr. Mark Cosentino
5107 Pegasus Court
Frederick, MD 21704

Contract No: N02-CP-11001

W.A. No: Modification No.: Date Prepared:

PART III. CONTRACTOR'S REPORT OF W.A. PERFORMANCE

(The Contractor may attach additional sheets to this form to present the requested data.)

A. Actual Cost and Effort

1. Labor hours - list specific assigned individuals, labor category, and actual hours worked.
2. Labor costs - list labor category, individual, and total amount.
3. Employee benefits
4. Direct Materials
5. Travel
6. Subcontracts
7. Other direct costs
8. Indirect costs
9. Total costs for this W.A.
10. Fee
11. Equipment
12. Total Estimated Cost and Fee

B. Report of Deliverables

REVIEW AND APPROVAL OF SATISFACTORY PERFORMANCE

The signatures below indicate that the services/products required under Work Assignment No. have been delivered, received and satisfactorily meet the requirements of this Work Assignment.

1. For the Contractor: _____ Date: _____
(Signature)

Typed name: _____

2. For the Government: _____ Date: _____
(Project Officer)

_____ Date: _____
(Contracting Officer)

INVOICE/FINANCING REQUEST INSTRUCTIONS
FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS, NIH(RC)-1

General: The contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

Format: Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal—Continuation Sheet," or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letter-head of self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission Clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the Payment Clause shall be submitted monthly unless otherwise authorized by the contracting officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include: (1) costs of a prior billing period, but not previously billed; or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. When payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the contracting officer's approval, which are not set forth in an Advance Understanding in the contract shall be so identified and reference the Contracting Officer's Authorization (COA) Number. In addition, any cost set forth in an Advance Understanding shall be shown as a separate line item on the request.

Invoice/Financing Request Identification: Each invoice/financing request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request —** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice —** The completion invoice is submitted promptly upon completion of the work; but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (whichever date is later). The completion invoice should be submitted when all costs have been assigned to the contract and all performance provisions have been completed.

(c) **Final Invoice —** A final invoice may be required after the amounts owed have been settled between the Government and the contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

(a) **Designated Billing Office Name and Address —** Enter the designated billing office name and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.

(b) **Invoice/Financing Request Number —** Insert the appropriate serial number of the invoice/financing request.

(c) **Date Invoice/Financing Request Prepared —** Insert the date the invoice/financing request is prepared.

(d) **Contract Number and Date —** Insert the contract number and the effective date of the contract.

(e) **Payee's Name and Address —** Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) **Total Estimated Cost of Contract —** Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) **Total Fixed-Fee —** Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.

(h) **Billing Period —** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) **Amount Billed for Current Period —** Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the period.

(j) **Cumulative Amount from Inception —** Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) **Direct Costs** — Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor** — Include salaries and wages paid (or accrued) for direct performance of the contract.

(2) **Fringe Benefits** — List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) **Accountable Personal Property** — Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHIIS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

- The item number for the specific piece of equipment listed in the Property Schedule.

- The COA letter and number, if the equipment is not covered by the Property Schedule.
- Be preceded by an asterisk (*) if the equipment is below the approval level.

Further itemization of invoices/financing requests shall only be required for items having specific limitations set forth in the contract.

(4) **Materials and Supplies —** Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) **Premium Pay —** List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee —** List fees paid to consultants. Identify consultant by name or category as set forth in the contract's advance understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) **Travel —** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs —** List subcontractor(s) by name and amount billed.

(9) **Other —** List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(l) **Cost of Money (COM) —** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) **Indirect Costs—Overhead —** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) **Fixed-Fee Earned —** Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.

(o) **Total Amounts Claimed —** Insert the total amounts claimed for the current and cumulative periods.

(p) **Adjustments —** Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(q) **Grand Totals**

The contracting officer may require the contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

SAMPLE INVOICE/FINANCING REQUEST

(a) Billing Office Name and Address

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute, RCB
EPS, Room
6120 EXECUTIVE BLVD MSC
Bethesda, MD 20892-

(b) Invoice/Financing Request No.

(c) Date Invoice Prepared

(e) Payee's Name and Address

ABC CORPORATION
100 Main Street
Anywhere, U.S.A. zip code

(d) Contract No. and Effective Date

(f) Total Estimated Cost of Contract

Attention: Name, Title, and Phone Number of Official to Whom Payment is Sent

(g) Total Fixed Fee

(h) This invoice/financing request represents reimbursable costs from Aug. 1, 1982 through Aug. 31, 1982

		(i) Amount Billed for Current Period	(j) Cumulative Amount From Inception
(k)	Direct Costs		
(1)	Direct Labor	$ 3,400	$ 6,800
(2)	Fringe Benefits	600	1,200
(3)	Accountable Personal Property (Attach Form HHS-565)		
	Permanent Research	3,000	6,000
	General Purpose	2,000	2,000
(4)	Materials and Supplies	2,000	4,000
(5)	Premium Pay	100	150
(6)	Consultant Fee-Dr. Jones 1 day @ 100 (COA #3)	100	100
(7)	Travel (Domestic)	200	200
	(Foreign)	200	200
(8)	Subcontract Costs	-0-	-0-
(9)	Other	-0-	-0-
	Total Direct Costs	$ 11,600	$ 20,650
(j)	Cost of Money (Factor) of (Approximate Base)	2,400	3,600
(m)	Indirect Costs — Overhead % of Direct Labor or Other Base (Formula)	4,000	6,000
(n)	Fixed-Fee Earned (Formula)	700	1,400
(o)	Total Amount Claimed	$ 18,700	$ 31,650
(p)	Adjustments		
	Outstanding Suspensions		(1,700)
(q)	Grand Totals	$ 18,700	$ 29,950

"I certify that all payments requested are for appropriate purposes and in accordance with the contract".

(Name of Official) (Title)

Note: Complete this form in accordance with Accompanying Instructions.

Persons

Reporting Period

Address

5107 Pegasus
Frederick, MD 21704

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost-Curent Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Negotiated Contract Amount	Variance (Over or Under) (I - H)
	Negotiated	Actual							
A	B	C	D	E	F	G	H	I	J
Direct Labor	139,205							$ 2,560,213	
Materials & Supplies								1,420,490	
Travel								4,885	
Equipment								1,228,197	
Moving expenses								83,040	
Other Direct Costs								339,762	
Total Direct Costs:								$ 5,636,587	
Overhead								3,533,094	
?A								641,876	
Total Proposed Cost:								$ 9,811,558	
[ILLEGIBLE] Fee								515,001	
Total CPFF								$ 10,326,558	

INSTRUCTIONS FOR COMPLETING FORM NIH 2706
"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. Form NIH 2706 is designed to: (1) provide a management tool for use by use NIH in monitoring the application of financial and personnel resources to the NIH contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any elements(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the reports(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later that 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the project officer.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate Form NIH 2706, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing Form NIH 2706. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel–Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two of more years, and sensitive items regardless of cost.

Form HHS 565, “Report of Accountable Property,” must accompany the contractor’s public voucher (SF 1034/SF 1035) or this report if not previously submitted. See “Contractor’s Guide for Control of Government Property.”

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Includes costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expenses.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on Form NIH 2706.

Column A—Expenditure Category. Enter the expenditure categories required by the contract.

Column B—Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C—Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D—Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the

end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E—Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F—Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G—Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H—Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I—Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J—Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

PRIVACY ACT SYSTEM OF RECORDS

[Federal Register: April 7, 1997 (Volume 62, Number 66)]
[Notices]
[Page 16596-16602]
From the Federal Register Online via GPO Access [wais. access.gpo.gov]
[DOCID:fr07ap97_dat-89]

[[Page 16596]]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Privacy Act of 1974; New System of Records

agency: National Institutes of Health, HHS.

action: Notification of a new system of records.

summary: In accordance with the requirements of the Privacy Act, the National Institutes of Health (NIH) is publishing a notice of a new system of records, 09-25-0200, "Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD." This system notice serves as an umbrella system for most NIH clinical, epidemiologic and biometric research studies. Thirty-eight existing NIH system notices were subsumed under this notice (listed in the system notice under System Manager(s)), to reduce the number and avoid future proliferation of like system notices. We are also proposing routine uses for this new system; with two exceptions, these routine uses were already contained in the preceding system notices. The first new routine use will allow disclosure to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions. The purpose of the disclosure is to plan for or provide such services, bill or collect third-party reimbursements. The second new routine use will allow disclosure for the purpose of reporting child, elder, or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

dates: NIH invites interested parties to submit comments on the proposed internal and routine uses on or before May 7, 1997. NIH has sent a report of a New System to the Congress and to the Office of Management and Budget (OMB) on November 6, 1996. This system of records will be effective 40 days from the date of publication unless NIH

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receives comments on the routine uses which would result in a contrary determination.

address: Please submit comments to: NIH Privacy Act Officer, Building 31, Room 1BO5, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075, 301-496-2832.
Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

for further information contact: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075, 301-496-2832.
The numbers listed above are not toll free.

supplementary information: The National Institutes of Health (NIH) proposes to establish a new system of records: 09-25-0200, "Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD." This umbrella system of records will be used by NIH staff to document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities. This inclusive system notice will achieve agency administrative efficiencies, avoiding confusion created by the current fragmented pool of Institute, Center and Division (ICD) system notices. Because of its unique organizational structure, NIH has, over the recent decades, experienced a proliferation of almost identical system notices that differ only by disease/disorder under study or ICD interest. This system notice subsumes thirty-eight existing system notices and will offer coverage for research not currently covered by an appropriate system notice. The consolidation of similar research systems of records into one generic type notice will also serve the public interest. It will alleviate burden on the public associated with multiple attempts at notification, access and correction of record information when individuals are not sure which research system notice applied to their study

participation.

The system will comprise records about individuals as relevant to a particular research study. Examples include, but are not limited to: Name, study identification number, address, relevant telephone numbers, Social Security Number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curriculum vitae); and associated correspondence. The amount of information recorded on each individual will be only that which is necessary to accomplish the purpose of the system.

The records in this system will be maintained in a secure manner compatible with their content and use. NIH and contractor staff will be required to adhere to the provisions of the Privacy Act and the HHS Privacy Act Regulations. The System Manager will control access to the

data. Only authorized users whose official duties require the use of such information will have regular access to the records in this system. Authorized users are HHS employees, and contractors responsible for implementing the research.

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. Manual and computerized records will be maintained in accordance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf:45-13, the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

Data on computer files is accessed by keyword known only to authorized users. Access to information is thus limited to those with a need to know. Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel. Researchers authorized to conduct research on biological specimens will typically access to the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual. All authorized users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Depending upon the sensitivity of the information in the record, additional safeguard measures are employed.

The routine uses proposed for this system are compatible with the stated purposes of the system. The first routine use permits disclosure of a record for an authorized research purpose under specified conditions. The second routine use permitting disclosure to a congressional office is proposed to allow subject individuals to obtain assistance from their representatives in Congress, should they so desire. Such

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disclosure would be made only pursuant to a request of the individual. The third routine use allows disclosure to the Department of Justice for use in litigation. The fourth routine use allows disclosure of records to contractor, grantee, experts, consultants or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. The fifth routine use allows disclosure to certain relevant third parties (e.g., relatives, prior employees, Motor Vehicle Administration, State vita statistics offices) when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. The sixth routine use allows disclosure to tumor registries for maintenance of health statistics. The seventh routine use allows the PHS to inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, or to disclose such information to State or local public health departments under specified circumstances. The

eighth routine use allows disclosure of certain diseases and conditions, including infectious diseases, to appropriate representatives of State or Federal Government as required by State or Federal law. The ninth routine use allows records to be disclosed to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements. The tenth routine use allows disclosure to organizations deemed qualified by the Secretary, DHHS, to carry out quality assessment, medical audits or utilization reviews. The eleventh routine use allows information to be disclosed for the purpose of reporting child, elder or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

The following notice is written in the present, rather than future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system has become effective.

Dated: October 30, 1996.
Anthony L. Itte?lag,
Deputy Director for Management, National Institutes of Health.
09-25-0200

SYSTEM NAME:

Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records are located at NIH and Contractor research facilities which collect or provide research data for this system. Contractors may include, but are not limited to: Research centers, clinics, hospitals, universities, medical schools, research institutions/foundations, national associations, commercial organizations, collaborating State and Federal Government agencies, and coordinating centers. A current list of sites, including the address of any Federal Records Center where records from this system may be stored, is available by writing to the appropriate Coordinator listed under Notification Procedure.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Adults and/or children who are the subjects of clinical, epidemiologic, and biometric research studies of the NIH. Individuals with disease. Individuals who are representative of the general population or of special groups including, but not limited to: Normal controls, normal volunteers, family members and relatives; providers of services (e.g., health care and social work); health care professionals and educators, and demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to real and/or hypothesized risks (e.g., exposure to biohazardous microbial agents).

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains data about individuals as relevant to a particular research study. Examples include, but are not limited to: Name, study identification number, address, relevant telephone numbers, Social Security Number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curriculum vitae); and associated correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

"Research and Investigation," "Appointment and Authority of the Directors of the National Research Institutes," "National Cancer Institute," "National Eye Institute," "National Heart, Lung and Blood-Institute," "National Institute on Aging," "National Institute on Alcohol Abuse and Alcoholism," "National Institute on Allergy and Infectious Diseases," "National Institute of Arthritis and Musculoskeletal and Skin Diseases," " National Institute of Child Health and Human Development," "National Institute on Deafness and Other Communication Disorders," "National Institute of Dental Research," "National Institute of Diabetes, and Digestive and Kidney Diseases," "National Institute of Drug Abuse," "National Institute of Environmental Health Sciences," "National Institute of Mental Health," "National Institute of Neurological Disorders and Stroke," and the "National Center for Human Genome Research," of the Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.)

PURPOSE(S)

To document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the

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record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a property identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when; (a) The agency or any component thereof; or (b) any employee of the agency in his or her official

capacity where the Department of Justice has agreed to represent the employee: or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

4. Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social Security numbers, date of birth and other identifiers may be disclosed: (1) To the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of

participants. Social Security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.

6. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in epidemiologic studies.

7. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) the PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b). PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

8. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

9. Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.

10. The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.

11. Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. For certain studies, factual data with study code numbers are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper/computer files.

RETRIEVABILITY:

During data collection stages and follow-up, retrieval is by

personal identifier (e.g., name, Social Security Number, medical record or study identification number, etc.). During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

SAFEGUARDS:

1. Authorized Users: Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

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Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the

individual.

2. Physical Safeguards: Records are either stored in locked rooms during off-duty hours, locked file cabinets, and/or secured computer facilities. For certain studies, personal identifiers and link files are separated and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.

3. Procedural Safeguards: Collection and maintenance of data is consistent with legislation and regulations in the protection of human subjects, informed consent, confidentially, and confidentiality specific to drug and alcohol abuse patients where these apply. When anonymous data is provided to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts fro survey and research activities related to this system. The OHS project directors, contract officers, and project officers oversee compliance with these requirements. Personnel having access are trained in Privacy Act requirements. Depending upon the sensitivity of the information in the record, additional safeguard measures may be employed.

4. Implementation Guidelines: DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the HHS General Administration Manual and Part 6, "ADP System Security" of the HHS ADP Systems Security Manual.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1 — "Keeping and Destroying Records" (HHS Records Management Manual,

Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Collaborative Perinatal Project records are retained in accordance with item 3000-G-4, which does not allow records to be destroyed. William A. White Clinical Research Program medical records (Saint Elizabeths Hospital, NIMH) are retained for 5 years after last discharge or upon death of a patient and then transferred to the Washington National Records Center, where they are retained until 30 years after discharge or death. Refer to the NIH Manual Chapter for specific conditions on disposal or retention instructions.

SYSTEM MANAGER(S) AND ADDRESS:

See Appendix 1 for a listing of current system managers. This system is for use by all NIH Institutes, Centers, and Divisions. The following system notices have been subsumed under this umbrella system notice.

09-25-0001 Clinical Research: Patient Records, HHS/NIH/NHLBI
09-25-0010 Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI
09-25-0015 Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINDS
09-25-0016 Clinical Research: Collaborative Perinatal Project, HHS/NIH/NINDS
09-25-0026 Clinical Research: Nervous System Studies, HHS/NIH/NINDS
09-25-0028 Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD
09-25-0031 Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS
09-25-0037 Clinical Research: The Baltimore Longitudinal Study of Aging, HHS/NIH/NIA
09-25-0038 Clinical Research: Patient Data, HHS/NIH/NIDDK
09-25-0039 Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK
09-25-0040 Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/ NIDDK
09-25-0042 Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR
09-25-0044 Clinical Research: Sensory Testing Research Program, HHS/NIH/ NIDR
09-25-0046 Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID
09-25-0053 Clinical Research: Vision Studies, HHS/NIH/NEI
09-25-0057 Clinical Research: Burkitt's Lymphonma Registry, HHS/NIH/NCI
09-25-0060 Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI
09-25-0067 Clinical Research: National Cancer Incidence Surveys, HHS/NIH/NCI
09-25-0069 NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI
09-25-0074 Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI

09-25-0077 Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI
09-25-0126 Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI
09-25-0128 Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS
09-25-0129 Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD
09-25-0130 Clinical Research: Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI
09-25-0134 Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences , HHS/NIH/NIEHS
09-25-0142 Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA
09-25-0143 Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID

09-25-0145 Clinical Trials and Epidemiological Studies Dealing with Visual Disease and Disorders in the National Eye Institute, HHS/NIH/NEI
09-25-0148 Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD
09-25-0152 Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR
09-25-0153 Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD
09-25-0154 Biomedical Research: Records of Subjects: 1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and 2) Women's Health Initiative (WHI) Studies , HHS/NIH/OD
09-25-0170 Diabetes Control and Complications Trial (DCCT) DataSystem, HHS/NIH/NIDDK
09-25-0172 Clinical Research: National Center for Human Genome Research, HHS/NIH/NCHGR
09-25-0201 Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH
09-25-0205 Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH
09-25-0212 Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH

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NOTIFICATION PROCEDURE:
To determine if a record exists, write to the appropriate ICD Privacy Act Coordinator listed below. In cases where the requestor

knows specifically which System Manager to contact, he or she may contact the System Manager directly (See Appendix I). Notification requests should include: Individual's name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and in specific cases, a notarized statement (some highly sensitive systems require two witnesses attesting to the individual's identity). A requestor must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the requestor is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.
Individuals will be granted direct access to their medical records unless the System Manager determines that such access is likely to have an adverse effect (i.e., could cause harm) on the individual. In such cases when the System Manager has determined that the nature of the record information requires medical interpretation, the subject of the record shall be requested to designate, in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. The representative may be a physician, other health professional, or other responsible individual. In this case, the medical/dental record will be sent to the designated representative. Individuals will be informed in writing if the record is sent to the representative. This same procedure will apply in cases where a parent or guardian requests notification of, or access to, a child's or incompetent person's medical record. The parent or guardian must also verify (provide adequate documentation) their relationship to the child or incompetent person as well as his or her own identity to prove their relationship.
If the requester does not know which Institute, Center or Division Privacy Act Coordinator to contact for notification purposes, he or she may contact directly the NIH Privacy Act Officer at the following address: NIH Privacy Act Officer, Office of Management Assessment, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075.

NIH Privacy Act Coordinators

Office of the Director, (OD), NIH
Associate Director for Disease Prevention, OD, NIH
Building 1, Room 260
1 Center Drive
Bethesda, MD 20892
National Cancer Institute (NCI)
Privacy Act Coordinator, NCI, NIH
Building 31, Room 10A34
31 Center Drive
Bethesda, MD 20892
National Eye Institute (NEI)
Privacy Act Coordinator, NEI, NIH

Building 31, Room 6A-19
31 Center Drive
Bethesda, MD 20892
National Heart, Lung and Blood Institute (NHLBI)

Privacy Act Coordinator, NHLBI, NIH
Building 31, Room 5A08
31 Center Drive
Bethesda, MD 20892

National Institute on Aging (NIA)
Privacy Act Coordinator, NIA, NIH
Building 31, Room 2C12
31 Center Drive
Bethesda, MD 20892

National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Privacy Act Coordinator, NIAAA, NIH
Wilco Building, Suite
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

National Institute of Allergy and Infectious Diseases (NIAID)
Privacy Act Coordinator, NIAID, NIH
Solar Building, Room 3C-23
6003 Executive Blvd.
Bethesda, MD 20892

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Privacy Act Coordinator, NIAMS, NIH
Natcher Building, Room SQS49
45 Center Drive
Bethesda, MD 20892

National Institute of Child Health and Human Development (NICHD)
Privacy Act Coordinator, NICHD, NIH
6100 Executive Blvd., Room 5D01
North Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders (NIDCD)
Privacy Act Coordinator, NIDCD, NIH
Building 31, Room 3C02
9000 Rockville Pike
Bethesda, MD 20892

National Institute of Dental Research (NIDR)
Privacy Act Coordinator, NIDR, NIH
Building 31, Room 2C-35
31 Center Drive, MSC 2290
Bethesda, MD 20892-2290

National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)
Privacy Act Coordinator, NIDDK, NIH
Building 31, Room 9A47
31 Center Drive
Bethesda, MD 20892

National Institute of Drug Abuse (NIDA)
Privacy Act Coordinator, NIDA, NIH
Parklawn Building, Room 10A-42

5600 Fishers Lane
Rockville, Maryland 20857

National Institute of Environmental Health Sciences (NIEHS)
Chief, Epidemiology Branch, NIEHS, NIH
P.O. Box 12233
Research Triangle Park
North Carolina 27709

National Institute of Mental Health (NIMH)
Privacy Act Coordinator, NIMH, NIH
Parklawn Building, Room 7C-22
5600 Fishers Lane
Rockville, Maryland 20857

National Institute of Neurological Disorders and Stroke (NINDS)
Privacy Act Coordinator, NINDS, NIH
Federal Building, Room 816
7550 Wisconsin Avenue
Bethesda, MD 20892

National Center for Human Genome Research (NCHGR)
Chief, Office of Human Genome Communications, NGHGR, NIH
Building 38A, Room 617

9000 Rockville Pike
Bethesda, Maryland 20892

RECORD ACCESS PROCEDURE:
Same as notification procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURE:
Contact the appropriate official at the address specified under Notification Procedure, and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:
The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: Referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological specimens; relatives; guardians; schools; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:
None.

Appendix I: System Managers and Addresses

Office of the Director, NIH

[[Page 16601]]

Associate Director for Disease Prevention, OD, NIH
Building 1, Room 260
1 Center Drive
Bethesda, MD 20892

National Cancer Institute
Computer Systems Analyst, DCBD, NCI, NIH
Executive Plaza North, Room 344
Bethesda, MD 20892

American Burkitt's Lymphoma Registry
Division of Cancer Etiology, NCI, NIH
Executive Plaza North, Suite 434
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Genetic Epidemiology Branch, EBP, DCE, NCI, NIH
Executive Plaza North, Suite 439
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Clinical Genetics Section
Clinical Epidemiology Branch, DCE, NCI, NIH
Executive Plaza North, Suite 400
6130 Executive Blvd.
Bethesda, MD 20892

Program Director, Research Resources
Biological Carcinogenesis Branch, DCE, NCI, NIH
Executive Plaza North, Room 540
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Environmental Epidemiology Branch, DCE, NCI, NIH
Executive Plaza North, Room 443
6130 Executive Blvd.
Bethesda, MD 20892

Associate Director, Surveillance Program, DCPC, NCI, NIH
Executive Plaza North, Room 343K
6130 Executive Blvd.

Bethesda, MD 20892

Head, Biostatistics and Data Management Section, DCT, NCI, NIH
8601 Old Georgetown Road
Bethesda, MD 20892

Chief, Clinical Research Branch
Biological Response Modifiers Program
Frederick Cancer Research and Development Center, DCT, NCI, NIH
501 W, 7th Street, Suite #3

Frederick, MD 21701

Deputy Branch Chief, Navy Hospital
NCI—Naval Medical Oncology Branch, DCT, NCI, NIH
Building 8, Room 5101
Bethesda, MD 20814

Chief, Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCT, NCI, NIH
Executive Plaza North, Suite 804
Bethesda, MD 20892

Director, Extramural Clinical Studies, BRB, BRMP, DCT, NCI, NIH
Frederick Cancer Research and Development Center
Fort Detrick
Frederick, MD 21701

National Eye Institute
Clinical Director, NEI, NIH
Building 10, Room 10N-202
10 Center Drive
Bethesda, MD 20892

Director, Division of Biometry and Epidemiology, NEI, NIH
Building 31, Room 6A-52
31 Center Drive
Bethesda, MD 20892

National Heart Lung and Blood Institute
Administrative Officer, Division of Intramural Research, NHLBI, NIH
Building 10 Room 7N220
10 Center Drive, MSC 1670
Bethesda, MD 20892-1670

Senior Scientific Advisor, OD
Division of Epidemiology and Clinical Applications, NHLBI, NIH
Federal Building, 220
7550 Wisconsin Avenue
Bethesda, MD 20892

National Institute on Aging
Computer Scientist, Longitudinal Studies Branch, IRP, NIH
Gerontology Research Center, GRC
4940 Eastern Avenue
Baltimore, MD 21224

Associate Director, Epidemiology,
Demography and Biometry Program, NIA, NIH
Gateway Building, Suite 3C309
7201 Wisconsin Avenue
Bethesda, MD 20892

National Institute on Alcohol Abuse and Alcoholism

Deputy Director, Division of Biometry and Epidemiology, NIAAA, NIH

Willco Building, Suite 514
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

Deputy Director, Div. of Clinical and Prevention Res., NIAAA, NIH
Willco Building, Suite 505
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

National Institute of Allergy and Infectious Diseases

Chief, Respiratory Viruses Section, LID, NIAID, NIH
Building 7, Room 106
9000 Rockville Pike
Bethesda, MD 20892

Chief, Hepatitis Virus Section, LID, NIAID, NIH
Building 7, Room 202
9000 Rockville Pike
Bethesda, MD 20892

Chief, Epidemology and Biometry Branch, DMID, NIAID, NIH
Solar Building, Room 3A24
Bethesda, Maryland 20892

Special Assistant, Clinical Research Program, DAIDS, NIAID, NIH
Solar Building, Room 2C-20
6003 Executive Blvd.
Bethesda, MD 20892

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Clinical Director, NIAMS, NIH
Building 10, Room 9S205
10 Center Drive
Bethesda, MD 20892

National Institute of Child Health and Human Development

Chief, Contracts Management Branch, NICHD, NIH
Executive Plaza North, Room 7A07
6100 Executive Blvd.
North Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders

Acting Director of Intramural Research, NIDCD, NIH
Building 31, Room 3C02
31 Center Drive
Bethesda, MD 20892

Director, Division of Human Communication, NIDCD, NIH
Executive Plaza South, Room 400B

6120 Executive Boulevard
Rockville, MD 20852

National Institute of Dental Research

Deputy Clinical Director, NIDR, NIH
Building 10, Room 1N-113
10 Center Drive, MSC 1190
Bethesda, MD 20892-1190

Research Psychologist, Clinical Invsetigations, NIDR, NIH
Building 10, Room 1N114
10 Center Drive, MSC 1190
Bethesda, MD 20892-1190

Chief, Contract Management Section
Extramural Program, NIDR, NIH
Natcher Building, Room 4AN-44B
45 Center Drive, MSC 6402
Bethesda, MD 20892-6402

National Institute of Diabetes and Digestive and Kidney Diseases
Chief, Clinical Investigations, NIDDK, NIH
Building 10, Room 9N222
10 Center Drive
Bethesda, MD 20892

Chief, Phoenix Clinical Research Section, NIDDK, NIH
Phoenix Area Indian Hospital, Room 541
4212 North 16th Street
Phoenix, Arizona 85016

Chief, Diabetes Research Section, DPB, DDEMD, NIDDK, NIH
Natcher Building, Room 5AN-18G
45 Center Drive, MSC 6600
Bethesda, MD 20892

National Institute on Drug Abuse
Privacy Act Coordinator, NIDA, NIH
Parklawn Building, Room 10A-42
5600 Fishers Lane
Rockville, Maryland 20857

National Institute of Environmental Health Sciences
Chief, Epidemiology Branch, NIEHS, NIH
P.O. Box 12233
Research Triangle Park
North Carolina 27709

National Institute of Mental Health
Director, Intramural Research Program, NIMH, NIH
Building 10, Room 4N-224
9000 Rockville Pike
Bethesda, MD 20205

Privacy Act Coordinator, NIMH, NIH
Parklawn Building, Room 7C22
5600 Fishers Lane
Rockville, Maryland 20857

Clinical Director, Neuroscience Research Center, DIRP, NIMH
Saint Elizabeths Hospital,
William A. White Building, Room 133
2700 Martin Luther King Jr., Avenue, SE
Washington, DC 20032

National Institute of Neurological Disorders and Stroke

[[Page 16602]]

Chief, Epilepsy Branch, NINDS, NIH
Federal Building, Room 114
7750 Wisconsin Avenue
Bethesda, MD 20892

Chief, Development Neurology Branch, NINDS, NIH
Federal Building, NIH
7550 Wisconsin Avenue
Bethesda, MD 20892

Assistant Director, CNP, DIR, NINDS, NIH
Building 10, Room 5N226
10 Center Drive
Bethesda, MD 20892

Deputy Chief, Laboratory of Central Nervous Systems Studies
Intramural Research Program, NINDS, NIH
Building 36, Room 5B21,
9000 Rockville Pike

Bethesda, MD 20892

Director, Division of Fundamental Neurosciences, NINDS, NIH
Federal Building, Room 916
7550 Wisconsin Ave
Bethesda, MD 20892

Director, Division of Convulsive, Developmental and Neuromuscular Disorders, NINDS, NIH
Federal Building, Room 816
7550 Wisconsin Avenue
Bethesda, MD 20892

Director, Division of Demyelinating Atrophic, and Dementing Disorders, NINDS, NIH
Federal Building, Room 810
7550 Wisconsin Avenue
Bethesda, MD 20892

Director, Division of Stroke and Trauma, NINDS, NIH
Federal Building, Room 8A08
7550 Wisconsin Avenue
Bethesda, MD 20892

National Center for Human Genome Research
Chief, Office of Human Genome Communications, NCHGR, NIH
Building 38A, Room 617
9000 Rockville Pike
Bethesda, MD 20892

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BILLING CODE 4140-01-M

HHSAR 352-223-70 SAFETY AND HEALTH (JANUARY 2001)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

PROCUREMENT OF CERTAIN EQUIPMENT

Notwithstanding any other clause in this contract, the Contractor will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the Contracting Officer.

67 - Phonographic Equipment
69 - Training Aids and Devices
70 - General Purpose ADP Equipment, Software, Supplies and Support (Excluding 7045-ADP Supplies and Support Equipment.)
71 - Furniture
72 - Household and Commercial Furnishings and Appliances
74 - Office Machines and Visible Record Equipment
77 - Musical Instruments, Phonographs, and Home-type Radios
78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the Contractor and determined essential by the Contracting Officer, the Government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

NIH(RC)-7 (4/1/84)
OMB Bulletin 81-16

ATTACHMENT 8

SCHEDULE I-B

ITEM	QUANTITY
LN_2 Freezer, XLC-1830	10
Racking System for LN_2's	10
Additional LN_2 Vacuum Piping	1
-70ºC So-Low Chest Freezers	75
Racking System for -70ºC's	75
Controlled Rate Freezer	1
Bar Coding Scanner	1
Computers	5
Cryo-Shipper	5
Flammable Storage Unit	1
Slide Storage Cabinet	1

Government Property Schedule 11-A

"Laboratory Support for Processing and Storage of Biological Specimens"

Job#	Item #	Piece#	Description	Gfp or Cap	Class	Mfr	Model	Serial No	Cost	Gov ID
129	OMF	051	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 1,780	01029103
129	OMF	053	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 1,780	01029102
129	OMF	055	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 1,780	01029104
129	OMF	056	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,680	01029124
129	OMF	057	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,539	01029117
129	OMF	058	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,850	01029105
129	OMF	059	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,729	01029129
129	OMF	060	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,539	01029118
129	OMF	061	Mechanical Freezer	CAP	Under	FORMA	????	69929-77	$ 4,539	01029116
129	OMF	062	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,850	01029106
129	OMF	063	Mechanical Freezer	CAP	Under	FORMA	????	60091-118	$ 4,539	01029119
129	OMF	064	Mechanical Freezer	CAP	Under	FORMA	????	60091-119	$ 4,539	01029120
129	OMF	066	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,732	01029121
129	OMF	067	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,680	01029123
129	OMF	068	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,680	01029125
129	OMF	069	Mechanical Freezer	CAP	Under	FORMA	????	11611-479	$ 4,680	01029126
129	OMF	070	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,275	01029127
129	OMF	071	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,275	01029128
129	OMF	072	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,857	01029130

129	OMF	073	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,857	01029131
129	OMF	074	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,857	01029132
129	OMF	075	Mechanical Freezer	CAP	Under	FORMA	????	13029-220	$ 4,743	01029133
129	OMF	076	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,743	01029134
129	OMF	077	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,743	01029135
129	OMF	078	Mechanical Freezer	CAP	Under	FORMA	????	13071-255	$ 4,743	01029136
129	OMF	079	Mechanical Freezer	CAP	Under	SOLOW	SE27,120	13071-256	$ 4,503	1023092
129	OMF	080	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 5,028	1029137
129	OMF	081	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 5,028	1029138
129	OMF	082	Mechanical Freezer	CAP	Under	SOLOW	SE27,120	????	$ 4,053	1023091
129	OMF	083	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,473	00811080
129	OMF	084	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 4,473	00811081
129	OMF	085	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 5,431	00811940
129	OMF	086	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 5,431	00811941
129	OMF	087	Mechanical Freezer	CAP	Under	SOLOW	SE27,120	????	$ 5,243	00871523
129	OMF	088	Mechanical Freezer	CAP	Under	SOLOW	SE27,120	????	$ 5,243	00871522
129	OMF	089	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 6,748	01175129
129	OMF	090	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 6,748	01175130
129	OMF	091	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 7,050	01096558
129	OMF	092	Mechanical Freezer	CAP	Under	FORMA	????	????	$ 7,050	01096559
129	OMF	093	Mechanical Freezer	CAP	Under	SOLOW	C15-27	????	$ 8,792	01182917
129	OMF	094	Mechanical Freezer	CAP	Under	SOLOW	C15-27	????	$ 10,080	01190561
129	OMF	095	Mechanical Freezer	CAP	Under	SOLOW	C15-27	????	$ 9,318	01190562
129	OMF	096	Mechanical Freezer	CAP	Under	SOLOW	C15-27	????	$ 9,318	01190563
129	OMF	048	Mechanical Freezer	CAP	Under	SOLOW	C15-27	????	$ 8,993	01264713
129	OMF	047	Mechanical Freezer	CAP	Under	SOLOW	C15-27	????	$ 8,993	01264714
129	OMF	045	Mechanical Freezer	CAP	Under	SOLOW	???-27	????	$ 9,268	01250392
129	OMF	046	Mechanical Freezer	CAP	Under	SOLOW	???-27	????	$ 9,268	01250393

129	OMF	043	Mechanical Freezer	CAP	Under	SOLOW	????-27	9697237	$ 9,808	01213988
129	OMF	044	Mechanical Freezer	CAP	Under	SOLOW	????-27	9697236	$ 9,808	01213989
129	OMF	Mbu1	Mechanical Freezer	CAP	Under	SOLOW	????-27	9697420	$ 5,525	01264570
129	OMF	Mbu2	Mechanical Freezer	CAP	Under	SOLOW	????-27	9697421	$ 5,525	01264571
129	OMF	#Mbu3	Mechanical Freezer	CAP	Under	SOLOW	????-27	????	$ 5,525	01264572
129	OMF	#Mbu4	Mechanical Freezer	CAP	Under	SOLOW	????-27	????	$ 5,525	01264573
129	OMF	#Mbu5	Mechanical Freezer	CAP	Under	SOLOW	????-27	????	$ 5,525	01264574
129	OMF	#Mbu6	Mechanical Freezer	CAP	Under	SOLOW	????-27	????	$ 5,525	01264575
129	OMF	#Mbu7	Mechanical Freezer	CAP	Under	SOLOW	????-27	????	$ 5,525	01264576
129	OMF	M1A	Cntrl Rare Frz-Prog	CAP	Under	????	????	????	$ 9,870	01029113
129	OMF	M1B	CRF-Chamber	CAP	Under	????	????	????		01029113
129	OMF	M2A	Cntrl Rare-Controller	CAP	Under	????	1010	????	$ 10,754	01029157
129	OMF	M2B	CRF-Recorder	CAP	Under	????	????	????		01029157
129	OMF	M2C	CRF-Chamber	CAP	Under	????	????	????		01029157
129	OMF	M3	LN2 Tank	CAP	Under	????	????	????	$ 1,295	1029156
129	OMF	M4	LN2 Dry Shipper	CAP	Under	????	CMD-20	CMD-20-1	$ 1,100	1029156
129	OMF	M5	Laminar Flow Hood	CAP	Under	????	????	????	$ 1,182	
129	OMF	M6	Laminar Flow Hood	CAP	Under	CCI	????	????	$ 8,952	
129	OMF	M7	Refrigerator	CAP	Under	????	????	????	$ 880	
129	OMF	M8	Water Bath	CAP	Under	????	????	????	$ 450	
129	OMF	M10	Hood, BioSafety	CAP	Under	????	????	????	$ 3,860	
129	OMF	M11	Freezer, Vertical	CAP	Under	????	????	????	$ 580	
129	OMF	M12	Freezer, Vertical	CAP	Under	????	????	????	$ 580	
129	OMF	M13	Microscope	CAP	Under	????	????	????	$ 11,956	
129	OMF	M14	Generator	CAP	Over	????	????	????	$ 40,300	
129	OMF	M15	Walk-in Refrigerator	CAP	Under	????	????	????	$ 7,776	
129	OMF	M16	Walk-in Freezer	CAP	Under	????	????	????	$ 9,250	

GOVERNMENT PROPERTY - SCHEDULE

CONTRACTOR: CONTRACT NUMBER

ADDRESS

REPORT DATE:

FISCAL YEAR:

SIGNED BY:

DATE SIGNED:

EXHIBIT 21.1

Subsidiaries of the Company as of February 2004

Name	Jurisdiction of Organization	Location
BBI Biotech Research Laboratories, Inc.	Massachusetts	Gaithersburg, MD
BBI Source Scientific, Inc.	Massachusetts	Garden Grove, CA
BBI BioSeq, Inc.	Massachusetts	Gaithersburg, MD

EXHIBIT 23.1

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-30320 and 333-24749), and Form S-3 (File Nos. 333-94379 and 333-46426) of Boston Biomedica, Inc. of our report dated March 27, 2003 relating to the financial statements as of December 31, 2002 and for the two years then ended and financial statement schedule as of and for the years ended December 31, 2002 and 2001, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 26, 2004

EXHIBIT 23.2

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 (File Nos. 333-30320 and 333-24749), and Forms S-3 (File Nos. 333-94379 and 333-46426) of Boston Biomedica, Inc. of our report dated March 4, 2004 relating to the consolidated financial statements and financial statement schedule, which appears in this Annual Report Form 10-K.

/s/ Weinberg & Company, P.A.

Boca Raton, Florida
March 26, 2004

EXHIBIT 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin W. Quinlan, President, Chief Operating Officer and Treasurer of Boston Biomedica, Inc., certify that:

1. I have reviewed this report on Form 10-K of Boston Biomedica, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) (Omitted)

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial data; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2004

/s/ Kevin W. Quinlan

Name: Kevin W. Quinlan
Title: President, Chief Operating Officer and Treasurer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael N. Avallone, Vice President, Finance and Chief Financial Officer of Boston Biomedica, Inc., certify that:

1. I have reviewed this report on Form 10-K of Boston Biomedica, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) (Omitted)

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial data; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2004

/s/ Michael N. Avallone

Name: Michael N. Avallone
Title: Vice President, Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report on Form 10-K of Boston Biomedica, Inc., a Massachusetts corporation (the "Company") for the period ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin W. Quinlan, President, Chief Operating Officer and Treasurer of Boston Biomedica, Inc., a Massachusetts corporation (the "Company"), do hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) that:

(1) The Report of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 26, 2004

/s/ Kevin W. Quinlan
Kevin W. Quinlan
President, Chief Operating Officer and Treasurer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Boston Biomedica, Inc. and will be retained by Boston Biomedica, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report on Form 10-K of Boston Biomedica, Inc., a Massachusetts corporation (the "Company") for the period ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael N. Avallone, Vice President, Finance and Chief Financial Officer of Boston Biomedica, Inc., a Massachusetts corporation (the "Company"), do hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) that:

(1) The Report of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 26, 2004

/s/ Michael N. Avallone
Michael N. Avallone
Vice President, Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to Boston Biomedica, Inc. and will be retained by Boston Biomedica, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.