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

Form 10-K/A

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Annual Report Pursuant to Section 13 or 15(d) of the Securities [X] Exchange Act of 1934 For the fiscal year ended December 31, 1999, 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

04-2652826

(State or other Jurisdiction of Incorporation or Organization) 375 West Street,

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

West Bridgewater, Massachusetts 02379-1040 -----

(Address of Principal Executive Offices) (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.

The aggregate market value of the voting common stock held by non-affiliates of the registrant at February 29, 2000 was \$49,248,992, based on the closing price of the common stock as quoted on the Nasdaq National Market on that date.

As of March 24, 2000 there were 5,441,960 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement involving the election of directors at its 2000 annual meeting, which is expected to be filed within 120 days after the end of the registrant's fiscal year, are incorporated by reference into Part III of this report.

PART I

Boston Biomedica, Inc. and its wholly-owned subsidiaries (together, "the Company"), provide products and services for the detection and treatment of infectious diseases such as AIDS, Lyme Disease, and Viral Hepatitis. The Company has four business units, which are comparable to operating segments (the terms "business units" and "operating segments" are used herein interchangeably):

- (1) BBI Diagnostics, an ISO 9001 certified manufacturer of quality control and other diagnostic products used to increase the accuracy of in vitro diagnostic tests;
- (2) BBI Clinical Laboratories, a leading infectious disease testing laboratory, specializing in nucleic acid based testing, tick borne diseases, and blood bank confirmatory testing;
- (3) BBI Biotech Research Laboratories, the research and development arm of the Company which supplements its support for the other BBI business units with research contracts and repository services primarily for agencies of the United States government; and
- (4) BBI Source Scientific, an ISO 9001 and EN 46001 certified manufacturer of laboratory and medical instruments.

In addition, the Company is pursuing research and development programs in the areas of Pressure Cycling Technology ("PCT") and drug discovery, with the goals of introducing new solutions for improving blood plasma safety, specimen preparation in nucleic acid testing, and treatment of infectious diseases.

The Company was organized in Massachusetts in 1978, and commenced significant operations in 1986.

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

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

In October 1999, the Company formed a new, wholly-owned subsidiary, Panacos Pharmaceuticals, Inc., ("Panacos"), a Delaware corporation. All of the Company's technology related to its drug discovery and vaccine programs, consisting primarily of patents and related sponsored research agreements, were transferred to Panacos effective January 2000. Management intends to sell a substantial portion of Panacos to third party investors in order to obtain the substantial amount of capital required to progress to more advanced stages of drug development including human clinical trials. If successful in raising capital, the Company plans to become a less than 50% shareholder in Panacos, give up operational control, and switch to the equity method of accounting for its investment, as opposed to consolidation accounting.

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

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# Industry Overview

Infectious Disease Test Kits and Testing Methods. Test kits contain in one compact package all of the materials necessary to run a test for an infectious disease. These materials include disposable diagnostic components,

instructions, and reaction mixing vessels (generally 96-well plates or test tubes) that are coated with the relevant infectious disease antigens, antibodies or other materials. To perform the test typically, either a technician or a specially designed instrument mixes the solutions from the test kit with human blood specimens in a specific sequence according to the test kit instructions. The mixture must then "incubate" for up to 18 hours, during which time a series of biochemical reactions trigger signals (including color, light or radioactive count), that indicate the presence or absence and amount of specific markers of the particular disease in the specimen.

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

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

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

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

Company Products and Services

## Overview

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

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Through its wholly-owned subsidiary, BBI Source Scientific, Inc., ("BBI Source"), the Company designs, manufactures and markets "Laboratory Instruments", consisting of readers and washers and other small medical devices. These instruments are used in hospitals and clinics, and in research, environmental and food testing laboratories. Utilizing a common hardware

technology platform, these instruments are used in connection with the performance of an IN VITRO diagnostics test, including reading the test result.

Through another wholly-owned subsidiary, BBI Clinical Laboratories, Inc. ("BBICL") the Company provides specialty clinical laboratory services that include both routine and sophisticated infectious disease testing in microbiology, immunology and molecular biology. BBICL seeks to focus its laboratory services in those advanced areas of infectious disease testing requiring special expertise.

BBI Biotech Research Laboratories, Inc., ("BBI Biotech"), another wholly-owned subsidiary, is the R&D "arm" of the Company, helping to develop new products and services for the other business units. BBI Biotech seeks to obtain government grants and other research support wherever possible to help fund the cost of this R&D. In addition, BBI Biotech provides repository services for the United States government, and other commercial services for laboratories and test kit manufacturers.

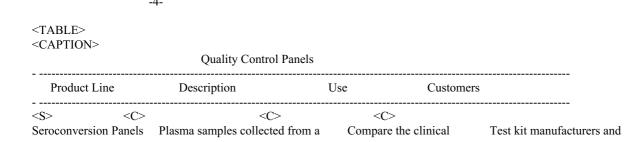
During each of the last three fiscal years, each of the Company's operating segments contributed at least 15% of the Company's consolidated revenue, with the exception of BBI Source in fiscal 1997 and 1999 and the "Other" segment in fiscal 1999. The Company's Consolidated Financial Statements set forth in Item 8 of this report provide financial information relating to each of the Company's operating segments.

#### Diagnostic Products

The Company manufactures its Diagnostic Products from human plasma and serum that are obtained from nonprofit and commercial blood centers, primarily in the United States. The Company has acquired and developed an inventory of approximately 30,000 individual blood units and specimens (with volumes ranging from 1 ml to 800 ml) which provides most of the raw material for its products. Within the Diagnostic Products class are two groups: Quality Control Products, consisting of QC Panels and Accurun(R) Run Controls, and Diagnostic Components.

## **Quality Control Panels**

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



single individual over a specific sensitivity of competing regulators. time period showing conversion from manufacturers' test kits, negative to positive for markers of enabling the user to assess an infectious disease. the sensitivity of a test in

> detecting a developing antigen/antibody.

Performance Panels A set of 10 to 50 serum and plasma Determine test kit performance Test kit manufacturers and samples collected from many different against all expected levels of regulators. individuals and characterized for the reactivities in the evaluation presence or absence of a particular of new, modified and improved test methods. disease marker.

Sensitivity Panels Precise dilutions of human plasma or Evaluate the low-end Test kit manufacturers.

serum human plasma or serum analytical sensitivity of a containing a known amount of an test kit. infectious disease marker as calibrated against international

standards.

Qualification Panels Dilutions of human plasma or serum Demonstrate the consistent Clinical reference manifesting a full range of lot-to-lot performance of test laboratories, blood banks, reactivities in test kits for a kits, troubleshoot problems, and hospital laboratories. specific marker. evaluate proficiency, and

train laboratory technicians.

Custom-designed Qualification Panels Train laboratory personnel on Custom designed with test kit OEM Panels for regulators and test kit new test kits or equipment. manufacturers and regulators manufacturers for distribution to as an end-user product or for

> customers or for internal use. internal use.

Verification Panels Verification Panels contain naturally Verify accuracy and ensure Clinical reference occurring undiluted samples at that reagents perform to laboratories, blood banks, expectation: also used to hospital laboratories. varying titers.

troubleshoot system problems and to document problem resolution.

#### </TABLE>

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

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

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

Accurun(R) Run Controls

End-users of test kits utilize run controls to confirm the validity of results by monitoring test performance, thereby minimizing false negative test results and improving 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 testtube, 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 measure whether the other, unknown specimens are being accurately tested. 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(TM) 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(R) family of products is targeted at the emerging market of end-users of infectious disease test kits. The Company believes that it offers the most comprehensive line of run controls in the industry, and that its Accurun(R) products, in combination with its Quality Control Panel 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(R) 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(R) Run Control products in the fourth quarter of 1993 and has since developed and released for sale an additional 46 Accurun(R) products. Two products have been discontinued, for a total of 48 Run Controls available as of December 31, 1999. The majority of these products are available for diagnostic purposes; the others currently are limited to research use. Current Accurun(R) Run Control products generally range in price from \$5 to \$60 per milliliter and are described in the following table.

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<TABLE> <CAPTION>

## ACCURUN(R) RUN CONTROLS

Product	-			Primary Customers
<s> Accurun 1(R) Multi Ma Positive Controls</s>	<c> arker Multi-marker diagnostic immunol</c>	<c> <c run controls for ogical tests</c </c>	> 12 hc	Blood banks, plasma centers, ospitals and clinical labs
Accurun Immunologica Controls	al Positive Single mark diagnostic immunologi	er run controls for cal tests	23	
Accurun Nucleic Acid Controls	Positive Single Marke	r run controls for tests	5	Research and specialty labs
Accurun Reference Nu Controls		s calibrated to the	2 and bl	International plasma manufacture lood centers
Accurun Negative Conii	trols Negative run c mmunological and nucleic esting	ontrols for	_	All labs

All of the Company's Accurun(R) Run Controls for diagnostic use require either FDA premarket clearance (a 510(k)) or validation studies (if the products are exempt from FDA submission requirements under the FDA Modernization Act of 1997), prior to being marketed for diagnostic use. As of March 1, 2000, a total of 12 products in the Accurun 1(R) line and 18 single analyte Accurun(R) controls have either received 510(k) clearance or have been validated.

#### Diagnostic Components

Diagnostic Components are the individual materials supplied to infectious disease test kit manufacturers and combined (often after further processing by the manufacturer) with other materials to become the various fluid components of the manufacturer's test kit. The Company supplies Diagnostic Components in four product lines: Normal Human Plasma, Normal Human Serum, Basematrix, and Characterized Disease State Serum and Plasma. Normal Human Plasma and Serum are both the clear liquid portion of blood which contains proteins, antibodies, hormones and other substances, except that the Serum product has had the clotting factors removed. Basematrix, the Company's proprietary processed serum product that has been chemically converted from plasma, is designed to be a highly-stable, lower cost substitute for most normal human serum and plasma applications. Characterized Disease State Serum and Plasma are collected from specific blood donors pre-selected because of the presence or absence of a particular disease marker. The Company often customizes its Diagnostic Components by further processing the raw material to meet the specifications of the test kit manufacturer. The Company's Diagnostic Components range in price from \$0.25 to \$60 per milliliter, with the majority selling between \$0.50 and \$5 per milliliter.

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#### Laboratory Instruments

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

Most of the Laboratory Instrumentation products currently being offered have been commercialized since 1985 and were primarily developed in conjunction with IN VITRO diagnostics test kit manufacturers. BBI Source hopes 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(R) Photometer. A compact, low-cost, photometer designed for immunoassay and general chemistry applications.

ChemStat(R) 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.

E/LUMINA(R) 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(R) Washing System. An automated immunoassay washing system that can be quickly configured by the user to wash different solid-phase assay formats by a propriety manifold design. The EXEC-WASH is fully compatible with a variety of other Company products, such as the ChemStat and the E/LUMINA II Luminescence Analyzer.

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

Verif-Eye(R) A reflectance reader for rapid, reliable results for use in research and development or process inspection and verification.

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

## Specialty Clinical Laboratory Testing

BBICL, the Clinical Laboratory Services operating segment, operates an independent specialty clinical reference laboratory that performs both routine and sophisticated infectious disease testing in microbiology, immunology and molecular biology, with special emphasis in AIDS, Viral Hepatitis, Lyme and other tick borne diseases, and comfirmatory testing for the blood bank industry. The Company's specialty clinical laboratory combines traditional microbiology, advanced immunology, and current molecular diagnostic techniques, such as PCR and bDNA, to detect and identify microorganisms, their antigens and related antibodies, and their nucleic acids (i.e., DNA and RNA).

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Specimens are picked up daily from customers, primarily by BBICL's courier staff, and are brought to the laboratory in New Britain, Connecticut for testing. There, they are received, accessioned, scheduled, and then tested. Results are returned to customers by fax, remote printers, data transmission and hard copy. BBICL emphasizes accuracy and turnaround time along with competitive pricing as keys to customer satisfaction. Customers include blood banks, physicians, clinics, hospitals and other clinical/research laboratories.

## Contract Research and Services

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

The Company currently provides contract research services under several contracts and grants. These services are primarily related to infectious disease diagnostics, in support of the products and services that the Company wishes to develop. Current contracts include the following: clinical trials support for candidate HIV vaccines; identification and DNA sequencing of human genes involved in neurological disorders, development of PCR based assays for Babesiosis and Transfusion Transmitted Virus, and microtiter plate assays for HIV-1 genotyping.

# Blood Processing and Repository Services

Since 1983, BBI Biotech has provided blood processing and repository services for the National Cancer Institute ("NCI"), also a part of the National Institutes of Health ("NIH"). The repository stores over 6,000,000 specimens and processes or ships up to several thousand specimens per week in support of various NIH cancer and virus research programs. In 1997, BBI Biotech was awarded a five-year (including renewal options) NCI repository contract with aggregate payments of up to \$4.8 million. In 1998, BBI Biotech received a six-year \$2.9 million repository contract (including five one-year extension options) with the National Heart, Lung and Blood Institute of the NIH, and in 1999, it received a seven-year, \$9.6 million repository contract with the National Institute of Allergy and Infectious Disease. To date all renewal options under these contracts have been approved, although the Company cannot be certain that any subsequent options will be exercised.

# Other Services

Clinical Trials. All four business units conduct 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.

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 and distribution.

After-sales Service. BBI Source also provides after-sales service. Management believes that after-sales service is a major marketing advantage in many of the Company's markets, since many of the Company's customers do not maintain their own full service departments. Servi-Trak(R), a proprietary software program, is a key element of this after-sales service. The Company's service department is located at BBI Source's facility in Garden Grove, California. The

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Company utilizes an independent third party contractor located in Giessen, Germany, to provide a fully functional European service and support center.

Drug Screening Program. As a subcontractor for an NIH AIDS grant held by the University of North Carolina at Chapel Hill, the Company has established an anti-HIV drug screening program to test a large number of natural products (largely plant derivatives) to determine whether they inhibit HIV replication in an in vitro assay system. These in vitro assays are also offered as a service to researchers and pharmaceutical companies who wish to test various candidate anti-viral agents for anti-HIV activity. The drug screening program and in vitro assays are now offered through the Company's newly formed subsidiary, Panacos Pharmaceuticals, Inc.

# Research and Development

The Company's research and development effort is focused on (i) the development of new and improved Quality Control Products (Panels and Accurun(R)) for the emerging end-user market and the in vitro diagnostics market, (ii) the expansion of its infectious disease testing services using PCR and other amplification assays, (iii) the design and development of new laboratory instruments and mechanical and optical detection techniques, emphasizing its Verif-Eye reflectance reader, (iv) the development of pressure cycling technology ("PCT") for nucleic acid purification and pathogen inactivation, and (v) the determination of the mechanism of action and performance of initial toxicity studies on its lead compounds in the Company's drug discovery program ("Panacos"). The Company has 36 full or part-time employees involved in its research and development effort. As announced in 1998, at the time of its acquisition of BioSeq, Inc., the Company has significantly increased spending on research and development both in whole dollars and as a percentage of revenue in 1999 as compared to 1998. See "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Results of Operations." The Company's research scientists work closely with sales, marketing, manufacturing, regulatory and finance personnel to identify and prioritize the development of new products and services. Whenever it can, the Company seeks to fund its research and development activities from grants provided by various agencies and departments of the United States government. See also "Contract Research and Services."

Quality Control Products. In the area of Quality Control Products, the Company's product development activities center on the identification and characterization of materials for the manufacture of new products and the replacement of sold-out products. During 1999, the Company introduced 14 new Seroconversion, Performance, and Qualification Panel products, 43 OEM Panels, as well as 13 new Accurun(R) Run Controls. The Company is developing new Quality Control Products for use with both immunological and molecular diagnostic tests for subtypes and variants of HIV, HCV and HBV, and a variety of controls targeted for leading instrument platforms. The Company has increased the number of Quality Control Products it offers from approximately 20 products in 1990 to

more than 200 in 1999.

Infectious Disease Tests. The Company also develops new and improved infectious disease tests, which the Company believes offer potential for above average profit, for sale by the Clinical Laboratory Services operating segment. Current emphasis is on additional PCR and other amplification technology based tests for infectious disease diagnostics, beyond the Company's current offerings of assays for the pathogens of AIDS, Lyme Disease, Viral Hepatitis, and Herpes, and for the direct detection of other infectious agents in blood, tissues and other bodily fluids.

Laboratory Instruments. The Company's product development activities related to laboratory instruments are centered on additional configurations of a "reflectance" reader to produce objective results from rapid in vitro diagnostic tests. In addition, the Company continues to work on applications for existing products to broaden their utilization.

Pressure Cycling Technology. BBI BioSeq, a wholly-owned subsidiary of the Company, owns patent pending technology based on PCT. PCT research is primarily focused in two areas: (1) nucleic acid extraction and purification from target pathogens in connection with sample preparation for PCR or other molecular testing; and (2) pathogen inactivation of blood plasma intended for transfusion or for further fractionation into transfusion products. See Note 2 to the Company's Notes to Consolidated Financial Statements in Item 8 hereunder for further details related to the 1998 acquisition of BioSeq, Inc.

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Drug Discovery. In August 1998, the Company hired a Vice President, Biotheraputics to direct its drug discovery and development efforts. In collaboration with Dr. K.H. Lee of the School of Pharmacy, University of North Carolina at Chapel Hill ("UNC"), the Company conducts research relating to compounds, pharmaceutical compositions, therapeutic methods, and vaccine preparations, primarily in the HIV field. The Company owns, jointly with UNC, five United States patents related to this drug discovery program. Two additional United States patent applications and foreign applications for all five of the joint patents are pending.

In April 1999, the Company increased its commitment to directly support the drug discovery program at UNC, in which a full-time, post-doctoral research scientist and two of Dr. Lee's doctoral students are working to develop synthetic derivatives of anti-HIV compounds that have been discovered pursuant to the Company's joint collaboration with UNC. These research scientists are also working to introduce modifications to these derivatives in an effort to make them more soluble, less toxic, or otherwise enhance their anti-viral properties. UNC has licensed to the Company exclusive worldwide rights to the five patents awarded to the Company and UNC. Two compounds covered under these patents have exhibited therapeutic indices in in vitro test model systems in excess of those recorded for AZT under comparable test conditions. Under this license, the Company will also have the rights to any new anti-HIV compounds or derivatives developed in the course of this sponsored research, provided the Company obtains certain regulatory approvals from the FDA.

In October 1999, the Company formed a new, wholly-owned subsidiary, Panacos Pharmaceuticals, Inc., ("Panacos") a Delaware corporation. All of the technology, intellectual property, sponsored research agreements, and related rights from the drug discovery business unit were transferred to Panacos effective January 2000. Management intends to sell a substantial portion of Panacos to third party investors in 2000 in order to obtain the substantial amount of capital required to progress to more advanced stages of drug development including human clinical trials. If successful in raising capital, the Company plans to become a less than 50% shareholder in Panacos, relinquish operational control, and switch to the equity method of accounting for its investment, as opposed to consolidation accounting.

## Sales and Marketing

The Company's sales and marketing efforts are managed on a business unit basis. Such activities are directed by a Director of Sales and Marketing for each unit. Overall, the Company employees 35 people in the sales, marketing, and customer service functions.

The Company's marketing strategy is to focus on the needs of its customers 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 Company also continues to focus its sales and marketing efforts on the emerging end-user market for Quality Control Products for infectious disease test kits. To promote this objective, the Company uses its marketing platform, known as "Total Quality System" ("TQS"). TQS is a package of Quality Control Products, including the Company's Accurun(R) Run Controls and AccuChart Quality Control Software, that is designed to provide test kit end-users with the products needed in an overall quality assurance program. These products enable laboratories to evaluate each of the key elements involved in the testing process: the test kit, laboratory equipment, and laboratory personnel. The Company believes that TQS effectively addresses the need for end-users to ensure the accuracy of their test results. The Company intends to continue to expand its sales and marketing activities with respect to its Accurun(R) 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 Products are currently sold through a combination of telephone, mail, third party distributors and direct sales efforts. Domestically, Diagnostic Products are sold through a direct sales force led by a Sales and Marketing director. The sales force consists of two sales group managers and 12 sales representatives. Internationally, the Company distributes its Diagnostic Products both directly and through 22 independent distributors located in Japan, Australia, South America, Southeast Asia, Israel and Europe. The Company's international sales

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manager oversees the Company's foreign distributors. The Company's Laboratory Instruments are sold through a direct domestic and international sales force consisting of one director and one sales representative.

The Company's Specialty Clinical Laboratory Testing services are marketed primarily through a direct domestic sales force, which consists of nine sales representatives managed by one regional manager, and a sales and marketing director. The sales representatives are located throughout the eastern, mid-western and western United States and are supported internally by a client services representative.

The Company emphasizes high quality products and services, technical knowledge, and responsiveness to customer needs in its marketing activities for both products and services. The Company educates its distributors, customers and prospective customers about its products through a series of detailed marketing brochures, technical bulletins and pamphlets, press 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. During 1999, the Company introduced a new product information library on the Company web site (www.bbii.com) allowing customers, field 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, driven by end-of-year expenditures, and seasonal demand during the summer months for certain laboratory testing services. 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 product. Specialty Clinical Laboratory Services have generally reached a seasonal peak during the third quarter, coinciding with the peak incidence of Lyme Disease. 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, Behring, Biorad, Chiron, Dade-Behring, DiaSorin, Fujirebio, Hoffman LaRoche, Ortho Diagnostics (Johnson & Johnson), and Sanofi Diagnostics. (2) regulatory agencies such as the United States FDA, 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 LabCorp, Quest Diagnostics, 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 Mast Immuno Systems, Beckman/Hybritech Inc., Vicam, and Toray Fuji Bionics Inc. The Company's customers for specialty clinical testing services include hospital and clinical laboratories, physicians, blood banks, researchers and other health care providers.

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The Company performs specialty testing services for a major state prison system in connection with a third party laboratory. 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 or its Specialty Clinical Testing Services, which are generally sold pursuant to purchase orders for discrete purchases. Laboratory Instruments are generally sold on an OEM basis under short-term contracts with monthly delivery dates. The Company believes that its relationships with customers are satisfactory.

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

During the fiscal years 1999, 1998 and 1997, sales to the Company's three largest customers accounted for an aggregate of approximately 16%, 18% and 20%, respectively, of the Company's net sales, although the customers were not identical in each period. During the fiscal years 1999, 1998 and 1997, the combined revenues to all branches of the National Institutes of Health, a United States Government agency, accounted for approximately 15%, 13% and 13%, respectively, of total consolidated revenues of the Company. While the Company believes that the loss of any one of these customers would have an adverse effect on the Company's results, this risk is partially mitigated by the diversity of its customer base within the in vitro diagnostics industry and the different diseases and instrument platforms on which they focus.

## Manufacturing and Operations

The Company manufactures and assembles Diagnostic Products at its facility in West Bridgewater, Massachusetts. Raw materials (primarily plasma and serum) are acquired from a variety of vendors and through a program of donor recruitment, screening, management, and plasma/serum collection and

characterization. Laboratory instruments are manufactured and assembled at the Company's facility in Garden Grove, California. All important raw materials and sub-assemblies are acquired from a variety of vendors with multiple sources of supply.

The Company operates its specialty clinical laboratory in New Britain, Connecticut, its research and development laboratory (including PCT and Panacos activities) in Gaithersburg, Maryland and a repository facility in Frederick, Maryland. See "Item 2 -- PROPERTIES."

## Competition

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

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

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

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

The Clinical Laboratory Services segment competes with large national reference laboratories, such as LabCorp of America and Quest Laboratories, as well as several independent regional laboratories, hospital laboratories, government contract laboratories and large research institutions. The Company believes that by focusing on the specialty clinical laboratory testing market, it is able to offer its customers a higher value-added service for the more complex diagnostic tests than the larger national reference laboratories.

BBI Biotech competes primarily with BioReliance Corporation and several universities for research and development contracts and with 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.

The Company has two United States patents related to its contracts and services work. Jointly with the Uiversity of North Carolina, at Chapel Hill, the Company has five additional United States patents relating to compounds, pharmaceutical compositions, therapeutic methods, and vaccine preparation in connection with the Company's drug discovery program. Two additional United States patents and foreign applications for all five of the joint patents are pending. The Company intends to continue to seek patent protection for innovations and discoveries arising out of the drug discovery programs.

The Company has fifteen pending patent applications for its Pressure Cycling Technology. Several of these have been followed up with foreign applications, and the Company expects to file additional foreign applications in 2000 relating to Pressure Cycling Technology. On March 14, 2000 the Company received notice from the United States Patent Office that one of its applications had been approved and the patent related to pressure cycling control of chemical reactions was issued to the Company.

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

BBI(R), Accurun(R), Microchem(R), Chemstat(R), E/LUMINA(R), EXECWASH(R) and Verif-Eye(R) are registered trademarks of the Company.

Government Regulation

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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(R) Run Controls, when marketed for blood donor screening or diagnostic use, have been classified by the FDA as medical devices that until 1998 required clearance under the 510(k) process. In 1998, new rules took effect that exempted unassayed controls intended for use in diagnostic testing from the requirement for a 510(k) submission. BBI may now label these products "For In Vitro Diagnostic Use" if they are validated according to the Company's protocols and manufactured according to cGMP (current Good Manufacturing Practices, which is FDA guidance for manufacturing processes for medical devices). The FDA still requires 510(k) clearance for assayed controls, and controls intended for use in blood screening. The FDA could, in addition, require that some products be reviewed through the PMA process, which generally involves a longer review period and the submission of more information to FDA.

The Company cannot be certain that it will obtain regulatory approvals on a timely basis, if at all. Failure to obtain regulatory approvals in a timely fashion or at all could have a material adverse effect on the Company.

As of March 1, 2000, a total of 13 products in the Accurun 1(R) line and 18 single analyte Accurun(R) controls have either received 510(k) clearance or have been validated according to the Company's protocols and are manufactured according to cGMP. Certain of the Company's Accurun(R) Run Controls are currently marketed "for research use only." The labeling of these products limits their use to research. It is possible, however, that some purchasers of these products may use them for diagnostic purposes despite the Company's intended use. In these circumstances, the FDA could allege that these products should have been cleared or approved by the FDA, or validated prior to marketing, and initiate enforcement action against the Company, which could have a material adverse effect on the Company. The FDA has issued a Draft Policy Compliance Guideline, which, if it takes effect as currently issued, will strictly limit the sale of products labeled "for research use only." The Company is monitoring this situation, and will adapt its policies as required.

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

The Company is registered as a medical device manufacturer with the FDA for its Diagnostic Products and Laboratory Instruments and files listings of its products semi-annually. The Company's facilities in West Bridgewater, Massachusetts for Diagnostic Products and Garden Grove, California for Laboratory Instruments are FDA Good Manufacturing Practices (FDA/GMP) facilities. The Company must maintain high standards of quality in manufacturing, testing and documentation, and implement strict cGMP 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 regulations governing testing, control, and documentation; and reporting of adverse experiences with the use of the device. The FDA monitors ongoing compliance with cGMP 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

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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 premarket 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 premarket approval or clearance. The Company cannot be certain, however, that the FDA would agree or that the FDA will not adopt a different interpretation of the FDCA or other laws it administers, which could have a material adverse effect on the Company.

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

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

The Company's service-related business (clinical trials, infectious disease testing, and contract research) 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 (such as the College of American Pathologists), and other national regulatory agencies (such as the Health Care Financing Administration). 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") regulations, investigational new drug or device regulations, Institutional Review Board ("IRB") regulations and informed consent regulations.

The Clinical Laboratory Improvement Amendments of 1988 ("CLIA") prohibits laboratories from performing in vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease, or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the US Department of Health and Human Services ("HHS") applicable to the category of examination or procedure performed.

The Company currently holds permits issued by HHS (CLIA license), 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 US Nuclear Regulatory Commission (in vitro testing with by-product material under general license, covering the use of certain radioimmunoassay test methods).

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

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an exempt small quantity generator of hazardous waste and has a US Environmental Protection Agency identification number. The Company is also registered with the US Nuclear Regulatory Commission for use of certain radioactive materials. The Company is also subject to various state regulatory requirements governing the handling of and disposal of biohazardous, radioactive and hazardous wastes. The Company has never been a party to any environmental proceeding.

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

## **Employees**

As of December 31, 1999 the Company employed 288 persons, all of whom were located in the United States. Of these, 107 persons were employed by the West Bridgewater, Massachusetts company, 78 by the New Britain, Connecticut company, 70 by the three Gaithersburg, Maryland companies, and 33 by the Garden Grove, California company. None of the Company's employees is covered by a

collective bargaining agreement. The Company believes that it has a satisfactory relationship with its employees.

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#### Executive Officers of the Registrant

The following table sets forth the names, ages and positions of the current executive officers of the Registrant as of December 31, 1999:

<table></table>		
<caption></caption>		
Name	Age P	osition
		<del></del>
<s></s>	<c> &lt;(</c>	
Richard T. Schumacher	49	Chief Executive Officer and Chairman of the Board
Kevin W. Quinlan	49	President and Chief Operating Officer; and Director
William R. Prather, R.Ph, I	M.D. 5	Senior Vice President, Finance and Business Development, Treasurer and
	Directo	or
Graham P. Allaway, Ph.D.	44	4 Senior Vice President, Drug Discovery
Patricia E. Garrett, Ph.D.	56	Senior Vice President and General Manager of BBI Clinical Laboratories
Mark M. Manak, Ph.D.	48	Senior Vice President and General Manager of BBI Biotech
David F. Petersen	53	Senior Vice President and General Manager of BBI Source
Richard C. Tilton, Ph.D.	63	Senior Vice President, Science and Technology
Barry M. Warren	52	Senior Vice President and General Manager of BBI Diagnostics
Kathleen W. Benjamin	43	Vice President, Human Resources
Richard D'Allessandro	53	Vice President, Information Technology
Ronald V. DiPaolo, Ph.D.	55	Vice President, Manufacturing

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

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

Dr. Prather, a Director of the Company since 1999, has been Senior Vice President, Finance and Business Development since July 1999. From January 1999 to August 1999, Dr. Prather served as Senior Vice President, Business Development. Prior to joining the Company, Dr. Prather was the Senior Health Care Analyst for the investment banking firm, Cruttenden Roth, Inc., from 1995 to 1998. From 1992 to 1995 he was the Senior Analyst in Health Care for Manning and Napier Advisors. Dr. Prather earned a B.S. in Pharmacy and an MD at the University of Missouri - Kansas City and completed a Clinical Research Geriatric Fellowship at Harvard Medical School. Dr. Prather is a Director of Primed International, a medical device company and a member of the Advisory Board of the Canadian Medical Discovery Fund, Inc., a fund of MDS Capital Corp.

Dr Allaway, has served as Vice President and Senior Vice President, Drug Discovery since joining the Company in 1998. Prior to that, from 1997 to 1998, he was CEO of Manchester Biotech (UK). From 1990 to 1997, Dr. Allaway served in various senior management positions including Associate Scientific Director and Head, Therapeutic Development Group at Progenics Pharmaceuticals, Inc., in Tarrytown, New York. From 1984 to 1990 Dr. Allaway was a Visiting Fellow and Visiting Associate at the NIH. Dr. Allaway received an M.A. in zoology from Oxford University and a Ph.D in virology from the University of London.

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

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

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

Dr. Tilton has served as Senior Vice President, Science and Technology since August 1999. Prior to this time he served as Senior Vice President, Specialty Laboratory Services since the Company's acquisition of BBI Clinical Laboratories, Inc. ("BBICL") in 1993 and was one of the founders of BBICL, serving as its President from 1989 to 1993. Dr. Tilton has 25 years of experience in university hospital clinical microbiology laboratories and is board certified in medical and public health microbiology. Dr. Tilton received his Ph.D. in microbiology from the University of Massachusetts.

Mr. Warren has served as Senior Vice President and General Manager of BBI Diagnostics since August 1999. From 1993 to 1999, he served as Senior Vice President, Sales & Marketing. From 1985 to 1993, Mr. Warren served as Group Director of Marketing of Organon Teknika, a manufacturer of infectious disease reagents. Mr. Warren received an M.A. in political science from Loyola University of Chicago and a B.A. from Loyola University.

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

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

Dr. DiPaolo has served as Vice President, Manufacturing since 1997. From 1993 to 1997, he served as Vice President of Operations. Prior to joining the Company, from 1986 to 1989, Dr. DiPaolo served as Vice President and General Manager of the Biomedical Products Division of Collaborative Research, a medical research products company. From 1975 to 1986, he was employed by DuPont New England Nuclear, an in vitro test kit manufacturer. Dr. DiPaolo received his Ph.D. in biochemistry from Massachusetts Institute of Technology and later

completed postdoctoral research at the Eunice Shriver Center in Waltham, Massachusetts.

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

#### ITEM 2. PROPERTIES.

The Company owns its corporate offices and diagnostic products manufacturing facility for its BBI Diagnostics operating segment, which is located in a two-story, 32,000 square foot building in West Bridgewater, Massachusetts. The Company has been renovating and expanding this facility during the past three years, and believes that upon completion of renovations, its facility in West Bridgewater will be sufficient to meet its needs for several years.

The Company leases 41,000 square feet of space in Garden Grove, California where its BBI Source business unit manufactures laboratory Instruments. The lease continues until February 1, 2002 and the Company has an option to renew at market rates.

The Company leases its laboratory facilities in Gaithersburg and Frederick, Maryland and New Britain, Connecticut. The BBI Biotech segment's Gaithersburg facility contains 36,500 square feet of custom built laboratory and office space, and is occupied under a ten-year lease that is due to expire on October 31, 2007. The Frederick facility contains 36,000 square feet of primarily repository space and is also occupied by the BBI Biotech segment, under a seven-year lease that is due to expire on November 30, 2006. The BBICL business unit occupies the New Britain facility which has 15,000 square feet of usable area, most of which is dedicated to laboratory space. This lease is due to expire on July 30, 2000; the Company has exercised its option to renew the lease for an additional five years.

The Company leased approximately 2,500 square feet of laboratory space in Woburn, Massachusetts through August 1999.

# ITEM 3. LEGAL PROCEEDINGS.

There are no material legal proceedings pending against the Company or its subsidiaries.

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

No matter was submitted during the fourth quarter of fiscal 1999 to a vote of security holders of the Company.

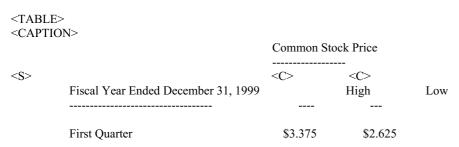
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#### PART II

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

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

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



Second Quarter	\$5.313	\$2.750
Third Quarter	\$4.562 	\$3.375
Fourth Quarter		\$2.750
Fiscal Year Ended December 31, 1998		
First Quarter	\$8.063	\$5.125 
Second Quarter	\$7.313	\$4.500
Third Quarter	\$5.125	\$2.500

</TABLE>

As of March 24, 2000, there were 20,000,000 shares of Common Stock authorized of which approximately 5,441,960 shares were outstanding, held of record by approximately 1,500 stockholders.

The Company has not declared or paid any dividends on its Common Stock. In accordance with the terms of the Company's loan agreement with its bank, payment of dividends on Common Stock requires bank approval. The Company does not expect to recommend the payment of a dividend as it plans to continue to reinvest profits to expand its business.

In October 1999, MdBio, Inc., an accredited investor, received 29,153 stock units in connection with its award of \$175,000 to the Company under a manufacturing incentive program that MdBio instituted. Each stock unit consists of one share of our common stock and a warrant to purchase on additional share of our common stock at an exercise price of \$10.00 per share. MdBio's warrants expire on September 29, 2003.

MdBio's warrants were not registered under the Securities Act of 1933, as amended, in reliance upon the exemptions from registration set forth in Sections 3(b) and 4(2) of that act, relating to sales by an issuer not involving any public offering. The MdBio transaction did not involve a public offering.

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## ITEM 6. SELECTED FINANCIAL DATA

The statement of income data for each of the fiscal years in the five year period ended December 31, 1999, and the balance sheet data as of December 31, 1999, 1998, 1997, 1996, and 1995, have been derived from the consolidated financial statements of the Company. These 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.

<TABLE>

<caption></caption>		Year Ende	d December 3	31,	
	1999	1998(1)	1997(2)	1996 1	995
Consolidated Statement of Income Data: <\$> REVENUE:	<c></c>	<c></c>	`	ds, except per	share data) C>
Products Services	\$ 14,05 15,21		5 \$ 11,711 10,588	\$ 8,470 7,039	\$ 6,622 5,649

Total revenue	29,271	26,081	22,299	15,509	12,271	
COSTS AND EXPENSES: Cost of products Cost of services Research and development Acquired research and development (3) Selling and marketing General and administrative	3, 4,02 <sup>4</sup> 4,4	259 2,46 4, 1 3,939 42 4,275	1 1,311 231 - 3,241 3,343	2,188 2,401	375  1,340	
	3				,494 11,763	
(Loss) income from operations Interest (expense) income, net	(4	(889) (4,90 (24) (51)	)2) 1,39 283	22 1,01:	5 508 (336)	
(Loss) income before income taxes and Benefit from (provision for) income taxes	l extraordinary i	tem (1,3 499	513) (4,953 564 (6	3) 1,675 670) (3)	802 21) (69)	172
Net (loss) income	\$ (814)	\$ (4,389)	\$ 1,005	\$ 481	\$ 103	
Net (loss) income per share, basic Net (loss) income per share, diluted	\$ ( \$	(0.17) \$ (0. (0.17) \$ (0	94) \$ 0.2 .94) \$ 0.	23 \$ 0.1 21 \$ 0.1	7 \$ 0.04 14 \$ 0.03	
Number of shares used to calculate net in	come per share					
Basic Diluted	4,670 4 4,670 4	,655 4, 1,655 4	438 2,9 ,780 3,	2,5° 340 2,5°	70 )40	
<caption></caption>		December 31	,			
	1999 1998	1997	1996	1995	-	
Consolidated Balance Sheet Data: <s></s>	<c> <c< td=""><td>(In tho</td><td>usands, exce</td><td>pt per share</td><td>data)</td><td></td></c<></c>	(In tho	usands, exce	pt per share	data)	
Working capital Total assets Long term debt, less current maturities Total stockholders' equity Dividends						

 26,162 | 24,082 7,146 3, | 23,650 989 2 18,067 | \$ 12,836 19,798 26 41 16,290 | 9,928 4,216 |  |

- (1) Effective September 30, 1998, the Company acquired all classes of stock of BioSeq, Inc., a development stage company with no revenue, for a total purchase price of \$4,226,000.
- (2) Effective July 1, 1997, the Company acquired the business and net assets of Source Scientific, Inc. for \$1,994,000 which increased 1997 revenue by \$2,608,000.
- (3) Consists of \$3,381,000 of in-process research and development related to the BioSeq acquisition, and a charge of \$850,000 related to the purchase of license technology in the first quarter of 1998.

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

## **OVERVIEW**

The Company generates revenue from products and services provided primarily to the IN VITRO diagnostic infectious disease industry. As discussed in Note 6 to the Consolidated Financial Statements, the Company has five operating segments: "Diagnostics," "BBI Biotech," "Clinical Laboratory Services," "Laboratory Instrumentation" and "Other.". Two of these, "Diagnostics" and "Laboratory Instrumentation" manufacture products, although the Laboratory Instrumentation segment also generates service revenue. Within Diagnostics there are three groups: Quality Control Panels, Accurun(R) Run

Controls, and Diagnostic Components. The remaining three segments generate service revenue and consist of "BBI Biotech", "Clinical Laboratory Services", and "Other" (Two development stage operations focused on research and development). Within BBI Biotech there are three groups: Contract Research, Blood Processing and Repository Services, and research services. Revenue in the "Other" segment consists of both private and NIH funded support for the research activities associated with our pressure cycling technology and drug discovery operations. See Note 6 for a further discussion of the activities of these segments.

#### **PRODUCTS**

The economics and cost structures of the segments have certain differences. The Diagnostics segment has historically been the largest and most profitable segment, both in whole 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 has been in decline for several years prior to its acquisition in mid 1997, and management is working to turn around this business. It also operates in a highly competitive, low margin business: contract manufacturing of instruments and devices. At the current low sales level of less than \$3 million in revenue, it operates significantly under capacity with high overhead, and should significantly benefit from relatively small revenue increases.

#### **SERVICES**

BBI Biotech has been project oriented with a high proportion of its revenue generated from government contracts (for both research and service activities) and assisting the other segments in their new product and service development. It has the highest level of inter-segment activity, and is structured around project tracking of direct costs plus overhead 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 Clinical Laboratory Services segment offers specialty infectious disease testing for hospital, doctors, blood banks and other reference laboratories on a fee per test basis. It operates in a segment of the healthcare field that continues to experience cost containment pressures, and has many competitors. The combination has resulted in operating margin pressures. The "Other" segment's two R&D operations do not currently have any product or service revenue, and none is expected in the near future. Their revenue to date consists of both private and public (NIH) funding of segment research. Most of the expenditures by this segment are for R&D expenses, and general management expenses including patent costs. The Company continues to seek funding from both

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private and public sources to minimize the impact of their development costs on the Company's overall operating results.

## 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, and seasonal demand during the summer months for certain laboratory testing services. 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. Clinical Laboratory testing services have generally reached a seasonal peak during the third quarter, coinciding with the peak incidence of Lyme Disease. In the Company's BBI 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 Other segment are subject to material seasonal variations.

#### RESEARCH AND DEVELOPMENT

With the acquisition of BioSeq, Inc and its pressure cycling technology in September 1998 as well as the hiring of a Vice President for the Drug Discovery and Development program and its subsequent formation of a new subsidiary ("Panacos Pharmaceuticals, Inc."), the Company has significantly increased its rate of research and development spending on new technologies in the Other operating segment. In addition, it has continued to focus on the development of new Quality Control Products and new tests for its clinical laboratory. Additional sales and support will be added as needed with the expectation of continued future revenue growth.

#### EXPORT SALES

The Company does not have any foreign operations. However, the Company does have significant export sales in Europe, the Pacific Rim countries and Canada to agents under distribution agreements, as well as directly to test kit manufacturers. All sales are denominated in US dollars. Export sales for the years ended December 31, 1999, 1998, and 1997 were \$4.0 million, \$4.1 million, and \$4.6 million, respectively. The Company expects that export sales will continue to be a significant source of revenue and gross profit.

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## 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:

<TABLE> <CAPTION>

	Year Ended December 31,			
	1999 1998 1997			
<s></s>	<c> <c> <c></c></c></c>			
Revenue:				
Products	48.0% 50.1% 52.5%			
Services	52.0 49.9 47.5			
Total revenue	100.0 100.0 100.0			
Gross profit	37.0 38.4 41.6			
Operating expenses:				
Research and Development	11.1 9.4 5.9			
	opment - 16.2 -			
Selling and marketing	13.7 15.1 14.5			
General and administrative	15.2 16.4 15.0			
Total operating expenses	40.0 57.1 35.4			
(Loss) income from operation	ons (3.0) (18.8) 6.2			
Interest income (expense)	(1.5) (0.2) 1.3			
(Loss) income before income Net (loss) income	e taxes (4.5) (19.0) 7.5 (2.8) (16.8) 4.5			
Product gross profit	48.3% 45.1% 50.7%			
Services gross profit	26.6% 31.6% 31.6%			

#### YEARS ENDED DECEMBER 31, 1999 AND 1998

#### **REVENUE**

Total revenue increased 12.2%, or \$3,190,000, to \$29,271,000 in 1999 from \$26,081,000 in 1998. The increase in revenue was the result of an increase in product revenue of 7.5% or \$982,000 to \$14,057,000 from \$13,075,000, and an increase in service revenue of 17.0% or \$2,208,000 to \$15,214,000 from \$13,006,000 in 1998.

PRODUCT REVENUE. The product revenue increase was primarily attributable to a \$700,000 increase by the Diagnostics segment and a \$287,000 increase by the Laboratory Instrumentation segment. The Diagnostics increase was a result of a 15.0% increase in Accurun(R) sales as the Company continued to successfully penetrate the emerging end-user market, and a 57.8% increase in Basematrix sales due to increased outsourcing occurring in the IN VITRO diagnostics industry. These increases were partially offset by a 22.7% decrease in Seroconversion Panel sales, as the consolidation within the IN VITRO diagnostic industry has negatively affected demand for these products. The Laboratory Instrumentation segment achieved a \$287,000 or 12.6% increase in instrument sales as it refocused its efforts in OEM contract manufacturing. Management feels that the end-user market will continue to be an area of growth for its Quality Control Products while the outsourcing within the IN VITRO diagnostics market will continue to benefit sales of Diagnostic Components and Laboratory Instrumentation.

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SERVICE REVENUE. The increase in service revenue was primarily attributable to a \$942,000 increase in BBI Biotech, a \$2,655,000 increase in Clinical Laboratory Services, and a \$434,000 increase in the Other segment revenue. Looking at the individual segments, BBI Biotech's growth was driven by a 43.9% increase in repository services and the start of new contracts in the AIDS Vaccine Support arena. The Clinical Laboratory Services' growth was led by a 55.1% increase in molecular testing. And the Other segment's growth was a result of funding received from both the NIH and the Consortium for Plasma Science, which partially defrayed the cost of pressure cycling technology development. These increases were partially offset by a \$1,293,000 decrease in Laboratory Instrumentation services as the Company completed its work on the ABX, Inc., contract in the first quarter of 1999. The Company anticipates that new contracts at the BBI Biotech segment and molecular testing at the Clinical Laboratory segment will also contribute to revenue growth.

## **GROSS PROFIT**

Overall gross profit increased 8.3%, or \$831,000, to \$10,835,000 in 1999 from \$10,004,000 in 1998. Product gross profit increased 15.2%, or \$894,000, to \$6,789,000 in 1999 from \$5,895,000 in 1998 and product gross margin increased to 48.3% in 1999, from 45.1% in 1998. Services gross profit decreased \$63,000 to \$4,046,000 in 1999 from \$4,109,000 in 1998 and service gross margin declined to 26.6% in 1999 from 31.6% in 1998.

PRODUCT GROSS MARGIN. The increase in product gross margin was due entirely to the gross margins realized in the Laboratory Instrumentation operating segment, which increased from 17.8% in 1998 to 28.1% in 1999 as the business unit operated at a higher volume, thus realizing better economies of scale compared with 1998 as overhead costs were spread over a greater number of units. Product gross margins at the Diagnostics segment remained relatively steady. Management anticipates that further utilization increases for the Laboratory Instrumentation segment will continue to benefit gross margins.

SERVICE GROSS MARGIN. The decrease in service gross margins was realized at all operating segments. The BBI Biotech segment's service gross margin decreased from 26.8% to 19.8%. BBI Biotech margins were adversely affected by startup costs associated with new repository contracts in 1999,

primarily the acquisition of freezers, which under the terms of the contract become government property and thus are charged directly to cost of sales. Also, the Clinical Laboratory Services segment realized service gross margins of 30.3% in 1999 versus 32.4% in 1998. This decrease is due to increased competition in the molecular testing arena, which created pricing pressure, negatively affecting margins. Finally, in early 1999 the Laboratory Instruments segment realized a decrease in service gross margins from 52.7% to 46.3%, as it completed the high-margin ABX, Inc. contract in early 1999. The Company feels that service margins will continue to feel pressure from increased competition in the clinical testing market. Furthermore as BBI Biotech expands its repository services, low-margin contracts will account for a greater portion of its total revenue if the Company is not continually successful in obtaining higher margin commercial services work. The other remaining Company segments do not generate service revenues that would significantly impact segment results.

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#### RESEARCH AND DEVELOPMENT

Research and development costs, exclusive of acquired in-process research and development, increased 32.4% or \$797,000 to \$3,259,000 in 1999 from \$2,461,000 in 1998. A significant portion of the increase is attributable to the operating segment referred to as "Other", which consists of the pressure cycling technology ("PCT") and Drug Discovery activities. The Company increased its PCT expenditures by approximately \$893,000 as it completed the design, development, and manufacture of 8 prototype PCT instruments known as "barocyclers". The Company also made significant progress during 1999 with its patents in the nucleic acid extraction and pathogen inactivation areas. The Company's increased expenditures in Drug Discovery by approximately \$361,000 resulted in expanded rights under its agreement with the University of North Carolina, at Chapel Hill, and significant progress in the prosecution of patents for the compounds. In addition, the BBI Biotech segment increased its spending to continue its support of the Diagnostics and Clinical Laboratory Services segments.

There were two accounting charges in 1998, which were classified on the income statement as acquired in-process research and development. In the first quarter there was an accounting charge of \$850,000 related to the acquisition of the worldwide exclusive rights to BioSeq, Inc.'s immunodiagnostic research and development technology. In the third quarter, the Company recorded a charge of \$3,381,000 related to in-process technology as a result of the Company's acquisition of BioSeq, Inc. This allocation of the purchase price was based on an independent valuation and was expensed, as no alternative future uses exist. There were no such charges during 1999.

# SELLING AND MARKETING

Selling and marketing expenditures remained relatively flat during 1999 as compared to 1998, across all operating segments. Costs increased only 2.2% or \$85,000 to \$4,024,000 in 1999 from \$3,939,000 in 1998 as the Company effectively managed costs in this area.

# GENERAL AND ADMINISTRATIVE

General and administrative costs increased 3.9% or \$166,000 to \$4,442,000 in 1999 from \$4,276,000 in 1998. This increase is attributable to the corporate reorganization that was announced in July of 1999. The reorganization created operating segments, which are directed by a senior vice president and general manager. The reorganization resulted in the classification of the salaries, and other related costs, of two executives in the general and administrative line of the income statement from other income statement lines, to more accurately reflect their new responsibilities. General and administrative costs are expected to increase in 2000, as the reorganization impact will be felt for the entire fiscal year 2000. In addition, 1999 benefited as certain general and administrative personnel costs were capitalized as property and equipment in connection with the implementation of enterprise resource planning systems at the Diagnostics and Laboratory Instruments segments.

General and administrative costs at the other segments were flat.

#### OPERATING LOSS

As a result of all of the above, the Company experienced an operating loss of \$889,000 versus \$4,902,000 in 1998. Excluding the \$4,231,000 of acquired in-process research and development charges realized in 1998, the Company's operating loss increased by 32.3% or \$217,000 to \$889,000 in 1999 from \$672,000 in 1998. The Diagnostics operating segment realized an increase in operating income of approximately \$225,000 or 40.3%, as a result of ed a a 15% increase in sales coupled with a relatively steady

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product gross margin. Clinical Laboratory Services operating segment realized a significant increase in operating income of approximately \$522,000 or 389.6%, as a result of a 37% increase in segment revenues which more than offset a slight decline in that segment's service gross margin. The Laboratory Instrumentation segment only realized a slight reduction, 8.1%, in its operating loss as the improved product gross margin was more than offset by lower service profitability due to the completion of the previously discussed ABX contract. These operational improvements were more than offset by the planned increases in research and development expenditures, which resulted in significant operating losses in the "Other" operating segment of \$1,345,000. In addition, the BBI Biotech segment also increased its research and development expenses resulting in a loss of \$152,000 in 1999 versus income of \$67,000 in the prior year. Management anticipates continued strength from its Diagnostics and Clinical Laboratory Services segments. Although the Laboratory Instrumentation segment has realized operating losses since it was acquired in July 1997, the Company believes that the goodwill created in connection with the acquisition is realizable as management believes that the segment will begin to generate operating income by the end of 2001. The Company will continue to increase its spending in the Other segment, however, it expects that the impact from this increased spending on the Company's bottom line will be mitigated by the planned sale of the common stock of Panacos and the continued funding support in the area of PCT.

The Company had net interest expense of \$424,000 in 1999 versus \$51,000 in 1998. The Company had used its proceeds from its initial public offering and, at the end of the second quarter of 1998, began to borrow funds from its revolving line of credit to continue its infrastructure and research and development investments. In addition to a higher average borrowing balance in 1999, the Company realized the effects of rising interest rates.

The Company recorded tax benefits at its combined federal and state statutory rate of 38% for 1999. Although the Company realized consolidated operating losses for 1999 and 1998 management believes that its valuation allowance is adequate as the Company plans to return to profitability within six to twelve months, at which point it will begin to realize benefit from its federal and state tax assets. The tax benefit rate recognized in 1998 was adversely affected by the in-process research and development charges discussed above. The March 1998 technology license transaction resulted in a temporary difference as the technology license is deductible for tax purposes over a 15-year period, while the September 1998 common stock acquisition resulted in a permanent difference that is never deductible. See Note 10 to Consolidated Financial Statements in Item 8 hereunder for further detail.

The Company had a net loss of \$814,000 in 1999 versus \$4,389,000 in 1998 as a result of the operating loss, the interest expense, and the effective tax rate described above.

## YEARS ENDED DECEMBER 31, 1998 AND 1997

In July 1997 the Company acquired the business of Source Scientific, Inc. The acquisition was completed by a wholly-owned subsidiary of the Company, BBI Source Scientific, Inc., ("BBI Source") and was accounted for as an asset

purchase. The income statement for 1997 includes the results of BBI Source for the last six months of the year, effecting comparability of results with 1998.

Total revenue increased 17.0%, or \$3,782,000, to \$26,081,000 in 1998 from \$22,299,000 in 1997. The increase in revenue was the result of an 11.6% increase in product revenue of \$1,364,000 to \$13,075,000 from \$11,711,000, and a 22.8% increase in service revenue of

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\$2,418,000 to \$13,006,000 from \$10,588,000 in 1997. Most of the product increase was attributable to increased sales of Quality Control Products achieved by the Diagnostics segment. The increase in such products was led by Accurun(R) which doubled in sales over the prior year. Also contributing to the increase in product sales was the inclusion of BBI Source (the Laboratory Instruments segment) for the full year in 1998 versus a half-year in 1997. The decrease in Quality Control Panel sales at the Diagnostics segment partially offset the product sales increases, as sales fell short of expectations due to consolidation in the IN VITRO diagnostic test kit industry. The BBI Biotech segment led the increase in service revenue with a 49.8% increase in contract research. Also contributing to the increase in service revenue was the Clinical Laboratory Testing segment, realizing a 19.5% increase in revenue.

Overall gross profit increased 7.7%, or \$717,000, to \$10,004,000 in 1998 from \$9,287,000 in 1997. Product gross profit decreased 0.7%, or \$43,000, to \$5,895,000 in 1998 from \$5,938,000 in 1997 and product gross margin decreased to 45.1% in 1998 from 50.7%. In 1997 the Diagnostics segment's product gross margin benefited from significant one-time sale of two "World-Wide Panels," which have unusually high gross margins due to their unique characteristics. These panels sold out in the first quarter of 1998, with minimal impact on 1998. The remaining product gross margin decrease was the result of lower capacity utilization at the Laboratory Instrumentation segment. Services gross profit increased 22.7%, or \$759,000, to \$4,109,000 in 1998 from \$3,350,000 in 1997 and gross margin remained steady at 31.6% in 1998 and 1997. Higher margins generated by the Contract Services and Laboratory Instrumentation segments offset the decrease in margins realized by the increased pricing pressure facing the Clinical Laboratory Testing segment

Research and development expenditures increased 87.7%, or \$1,150,000, to \$2,461,000 in 1998 from \$1,311,000 in 1997. The increase was realized across all of the segments. The Laboratory Instrumentation segment invested in new reflectance technology for its Verif-Eye product line. The Diagnostics segments also increased its development expenditures, specifically for development of Accurun(R) molecular and immunological Run Controls. The Company invested in development of new specialized molecular assays for use by the Clinical Laboratory Testing segment. Finally, the Company began the development of PCT as it acquired BioSeq, Inc (one component of the Other segment) in September 1998.

There were two accounting charges during the twelve months ended December 31, 1998, which were classified on the income statement as acquired in-process research and development. In the first quarter there was an accounting charge of \$850,000 related to the acquisition of the worldwide exclusive rights to BioSeq Inc.'s immunodiagnostic research and development technology. In the third quarter, the Company recorded a charge of \$3,381,000 related to in-process technology as a result of the Company's \$4,226,000 acquisition of BioSeq, Inc.

Selling and marketing expenses increased 21.5%, or \$698,000, to \$3,939,000 in 1998 from \$3,241,000 in 1997. The increase was attributable primarily to inclusion for a full year in 1998 of the expanded TQS sales, marketing, and technical support staff added to the Diagnostics segment in the spring of 1997. The Company also expanded its presence at tradeshows, resulting in higher expenditures in this category.

General and administrative costs increased 27.9%, or \$933,000, to \$4,276,000 in 1998 from \$3,343,000 in 1997. This increase was attributable

primarily to additional support staff, and increased information systems consulting and investor relations activities at the Diagnostics segment, which includes the majority of the corporate functions and officers for both periods. In addition, the inclusion of the Laboratory Instrumentation segment for a full year added \$412,000 of expense to this category.

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As a result of all of the above, the Company experienced an operating loss of \$4,902,000 versus income of \$1,392,000 in 1997. This decrease was primarily a result of the acquired in-process research and development expense, a higher operating loss at the Laboratory Instrumentation segment, increased research and development expenditures at all segments, and lower profitability at its Diagnostics and Clinical Laboratory Testing operating segments.

The Company had net interest expense of \$51,000 in 1998 versus interest income of \$283,000 in 1997. The Company had used the proceeds from its initial public offering and, at the end of the second quarter of 1998, began to borrow funds from its revolving line of credit to continue its infrastructure and research and development investments.

The Company provided taxes at the combined federal and state rate of 38% for 1998 versus 40% in the prior year. The rate decrease was the result of offsetting the Massachusetts taxable income of the Diagnostics operating segment with the Massachusetts losses of BBI BioSeq, Inc., This benefit was adversely impacted by the tax treatment of the acquired in-process technology from BioSeq, Inc. as the acquisition was structured as a stock purchase. Therefore, the effective benefit rate for 1998 was approximately 11%.

The Company had a net loss of \$4,389,000 in 1998 versus net income of \$1,005,000 in 1997 as a result of the operating loss described above and a shift to interest expense in 1998 versus interest income in 1997.

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## LIQUIDITY AND CAPITAL RESOURCES

At December 31, 1999, the Company had cash and cash equivalents of approximately \$315,000 and working capital of \$10,053,000. Gross trade accounts receivable increased \$483,000 or 7.2% as a result of a 7.8% increase in revenues in the fourth quarter of 1999 versus the same period in 1998. Inventory increased \$228,000 or 3.4%, related primarily to work-in-process for upcoming projects within the Diagnostics segment.

The Company has financed its operations to date through cash flow from operations, borrowings from banks and the sale of its common stock. The Company expects its cash flow, working capital, and available borrowings under its revolving line of credit to meet existing operational needs in 2000. In mid 1999 the Company and its bank agreed to a modified borrowing agreement with revised financial covenants, which the Company expects will meet existing operational needs for the foreseeable future. At December 31, 1999 the Company was in compliance with its financial covenants.

In addition, in March 2000 the Company received a signed term sheet from a bank for a mortgage of the Company's West Bridgewater, MA facility. The Company anticipates that it will complete the transaction in the beginning of the second quarter of 2000. The Company intends to use the \$2,500,000 of cash generated to pay down its existing line of credit.

Net cash used in operations for 1999 was \$657,000 as compared to \$1,215,000 in 1998. This decrease in operational use of cash is due to improved

management of working capital, including better utilization of inventory and more effective management of payables and receivables. The \$123,000 increase in reserve for doubtful accounts partially offset this improvement of operational cash flow. The Company increased its reserve because there has been a gradual shift in the Company's customer mix from large, well known, IN VITRO diagnostics manufacturers to a more diversified customer matrix, which includes smaller, less established companies. While the Company has not yet experienced a significant increase in write-off's as a result of this shift, management feels that establishing the current level of reserve is prudent.

Cash used in investing activities for 1999, 1998 and 1997 amounted to \$2,731,000, \$5,462,000, and \$5,396,000, respectively. Substantially all of the investing activities in 1999 related to additions of property and equipment. These expenditures included approximately \$1,138,000 of computer hardware and software, including approximately \$807,000 invested in new enterprise resource planning systems for the Diagnostics and Laboratory Instrumentation segments. The BBI Biotech segment spent approximately \$522,000 on leasehold improvements as it prepared a new facility in Frederick, Maryland for the repository contract with the National Institute of Allergy and Infectious Disease, Division of AIDS. In addition, the Company continued construction at its BBI Diagnostics facility in West Bridgewater, Massachusetts as it spent approximately \$352,000 improving this manufacturing facility. In 1998, three major items accounted for most of the Company's investing activities. First, effective September 30, 1998, the Company completed the acquisition of the remaining common stock of BioSeq. Inc.. for a cash expenditure of \$2,557,000. Second, \$1,460,000 was expended for additional improvements at the Company's Massachusetts and Maryland facilities. Finally, \$437,000 was spent on software, hardware and implementation costs for the enterprise resource planning system. In 1997, four items accounted for most of the investing activities. First, the Company exercised its option to purchase an additional 165,000 shares of BioSeq, Inc. stock at an aggregate cost of \$750,000, thereby increasing its ownership of BioSeq to 19.9%. Second, in May 1997, the Company's BBI Biotech subsidiary signed a ten year lease for new laboratory space in Gaithersburg, Maryland and spent \$566,000 on leasehold improvements for new laboratory space for its contract research and product development activities. Third, the expansion and renovation of its BBI Diagnostics manufacturing facility in West Bridgewater, Massachusetts, commenced

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construction and approximately \$920,000 was expended. Finally, the Company completed the acquisition of Source Scientific, Inc. at a purchase price of \$1,994,000 including acquisition costs.

During 1999, net cash provided by financing activities was approximately \$3,555,000 from a combination of net borrowings of \$3,164,000 under the revolving line of credit, and proceeds of \$206,000 from the sale of stock and stock warrants to third party investors. In addition, the Company realized proceeds of \$148,000 and \$37,000 from the sale of stock and the exercise of stock options, respectively. During 1998, net cash provided by financing activities was \$4,052,000 from a combination of net borrowings of \$3,963,000 under the revolving line of credit, and proceeds of \$89,000 from the exercise of stock options. During 1997, net cash generated from financing activities included \$300,000 from the exercise of warrants, and \$182,000 from exercising stock options. Also in 1997, \$1,124,000 was used to pay down debt acquired in connection with the Source acquisition.

The Company anticipates significant capital expenditures in 2000 to continue as it plans to compete renovations to its manufacturing facility in Massachusetts and its repository facility in Frederick, Maryland. In addition to the renovations, the Company intends to continue its enterprise resource planning system implementation, as it installs new systems at BBICL and BBI Biotech. The Company believes that existing cash balances, the borrowing capacity available under the revolving line of credit, cash generated from operations and proceeds from the issuance of its common stock are sufficient to fund operations and anticipated capital expenditures in 2000. Except for purchase orders in connection with the manufacturing expansion, there were no material financial commitments for capital expenditures as of December 31, 1999.

In February of 2000, the Company received notice that certain warrant holders exercised 500,000 warrants. This exercise will result in proceeds to the Company of approximately \$2,100,000, net of transaction costs, when the transaction closes, pursuant to completing the registration of the underlying shares.

#### YEAR 2000 READINESS DISCLOSURE

Our Year 2000 ("Y2K") program was designed to minimize the possibility of serious Year 2000 interruption. In 1997 the Company decided to significantly upgrade its "business system" (all computer hardware and software used to run its business including its operations management, administration and financial systems).

Specifications were developed for desired capabilities, including Year 2000 compliance and the Company began to assess various enterprise resource planning systems ("ERP System") in 1998. Additionally, the Company organized a task force at each operating segment to review other infrastructure areas including communications systems, building security systems and embedded technologies in areas such as laboratory instruments and manufacturing equipment. The Company also began to survey mayor suppliers, distributors, and customers to determine the status and schedule for their Year 2000 compliance.

During the fourth quarter of 1999 the Company completed the ERP implementation at the two of the Company's subsidiaries. The other subsidiaries received upgraded, Year 2000 compliant versions of existing software. The Company spent less than \$200,000 to prepare for Y2K. This amount includes the cost to upgrade existing software packages to compliant versions, use of existing resources to execute surveys and measure results, and incremental costs associated with other infrastructure areas. This amount excludes all costs associated with the implementation of the ERP Systems which was completed for reasons beyond Y2K compliance.

Possible Year 2000 worst case scenarios include the interruption of significant parts of our business as a result of internal business system failure or the failure of the business systems of the Company's suppliers, distributors or customers. Any such interruption may have a material adverse impact on our future results. Although no significant problems have been noted to date, the Company acknowledges that there is still risk that such problems may occur. Any such interruption could have a material adverse impact on the future results of the Company.

## Recent Accounting Pronouncements

Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities" (SFAS 133) is effective, as amended for quarters of fiscal years beginning after June 15, 2000. The new standard requires companies to record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivatives and whether they qualify for hedge accounting. The key criterion for hedge accounting is that the hedging relationship must be highly effective in achieving offsetting changes in fair value or cash flows. The Company does not currently engage in derivative trading or hedging activity.

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In December 1999, the Staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). This SAB summarizes certain of the Staff's views in applying generally accepted accounting principles, in the United States, to revenue recognition in financial statements. SAB 101 is effective for the Company's quarter ended June 30, 2000. The Company does not expect the provisions of SAB 101 to have a material impact on its financial statements.

## Forward - Looking Information

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

Factors which might cause actual results to differ materially from those projected in the forward-looking statements contained herein include the following: finalization of SEC guidelines for valuation of in-process research and development as it relates to purchase accounting; inability of the Company to develop the end-user market for quality control products; inability of the Company to integrate the business of Source Scientific, Inc. into the Company's business; inability of the Company to grow the sales of Source Scientific, Inc. to the extent anticipated; the renewal and full funding of contracts with National Institutes of Health (NIH), National Heart, Lung and Blood Institute (NHLBI) and other government agencies; the inability of the Company to develop the technology recently acquired as part of its purchase of BioSeq, Inc. to the level of commercial utilization; the inability of Panacos to obtain sufficient funding to progress to more advanced stages of development, the failure of Panacos to identify and successfully commercialize any new drugs or vaccines, the inability of the Company to obtain an adequate supply of the unique and rare specimens of plasma and serum necessary for certain of its products; significant reductions in purchases by any of the Company's major customers; the interruption of significant parts of the Company's business as a result of internal business system failure or the failure of the business systems of its suppliers, distributors or customers due to the inability of such systems to properly interpret dates subsequent to December 31, 1999; and the potential insufficiency of Company resources, including human resources, plant and equipment and management systems, to accommodate any future growth. Certain of these and other factors which might cause actual results to differ materially from those projected are more fully set forth under the caption "Risk Factors" in the Company's Registration Statement on Form S-1 (SEC File No. 333-10759).

# 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, 1999 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, 1999, 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, the largest customer (approximately 15% of 1999 consolidated revenue) was the NIH, a U.S. Government agency. The Company is exposed to credit-related risks associated with its trade accounts receivable denominated in U.S. Dollars but receivable from foreign customers.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

<TABLE> <CAPTION>

December 31,

1999 1998

-----

## **ASSETS**

CI	<b>IR</b>	RI	FNT	ΓΔ	SS	FΠ	rg.	
·ι	JIN	NI	N I	_	$\cdot$	1 2 1		

<S>

Cash and cash equivalents \$ 314,923 \$ 146,978

<C>

<C>

Accounts receivable, less allowances of \$746,797 in 1999 and

\$623,710 in 1998 6,446,318 6,086,693 Inventories 6,917,916 6,689,768 Prepaid expenses 344,353 479,983 Deferred income taxes 934,790 847,268

Total current assets 14,958,300 14,250,690

Property and equipment, net 8,295,024 6,925,423

OTHER ASSETS:

Goodwill and other intangibles, net 2,809,825 2.589.310 Deferred income taxes 220,535

Notes receivable and other 99,171 96,447

2,909,016 2,906,272

TOTAL ASSETS \$26,162,340 \$24,082,385

## LIABILITIES AND STOCKHOLDERS' EQUITY

## **CURRENT LIABILITIES:**

Accounts payable	\$ 2,552,268	\$ 2,369,495
Accrued compensation	1,189,140	1,284,162
Accrued income taxes	112,487	
Other accrued expenses	1,028,667	795,642
Current maturities of long term debt	22,414	15,569
Deferred revenue		690,760
Total current liabilities	4,904,976	5,155,628

4,904,976

# LONG-TERM LIABILITIES:

Long term debt, less current maturities 7,145,651 3,988,602

Other liabilities 465,590 730,138 Deferred income taxes 139,363

## COMMITMENTS AND CONTINGENCIES

## STOCKHOLDERS' EQUITY:

Common stock, \$.01 par value; authorized 20,000,000 shares in 1999 and 1998; issued and outstanding 4,773,365 in 1999 and

4,667,816 in 1998 46,679 47,734 Additional paid-in capital 16,809,242 16,418,716 Accumulated deficit (3,210,853)(2,396,741)

Total stockholders' equity 13,646,123 14,068,654

TOTAL LIABILITIES & STOCKHOLDERS' EQUITY

</TABLE>

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

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# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF INCOME

<TABLE> <CAPTION>

Years Ended December 31,

\$ 26,162,340

\$ 24,082,385

	1999	1998	19	97	
<\$>	<c></c>	<c></c>	·	~>	
REVENUE:				<i>5</i> .	
Products	\$ 14,056	,657 \$ 1	3,075,083	5 \$11	,711,026
Services	15,214,				
Total revenue	29,27	1,088			2,299,337
COSTS AND EXPENSES:					
Cost of products	7,26	57,273	7,179,92	0 5,	773,417
Cost of services	11,16	58,595	8,897,04	6 7,	238,527
Research and development		3.258.542	2.40	61.316	1.311.190
Acquired research and development			4,23	30,812	
Selling and marketing	4,	,023,791	3,938,	753	3,241,422
General and administrative		4,441,524	4,27	5,627	3,241,422 3,342,829
Total operating costs and expenses		30,159,72	25 30	),983,474	20,907,385
(Loss) income from operations		(888,637	(4,9	902,398)	1,391,952
Interest income	6,	146	27,901	295,	998
Interest expense	(430	146 0,593)	(78,621)	(1	3,227)
-					
(Loss) income before income taxes		(1,313,0	84) (4	4,953,118	1,674,723
Benefit from (provision for) income taxes		498,9	972	564,399	(669,889)
Net (loss) income		14,112)			1,004,834
Net (loss) income per share, basic		\$ (0.17)	\$ (	0.94) \$	0.23
Net (loss) income per share, diluted		\$ (0.17)	\$ (	(0.94)	\$ 0.21
Number of shares used to calculate net (los	s) income p	er share			
Basic		17 4,65	54,609	4,437,	801
Diluted					

 4,669,7 | 17 4,6 | 554,609 | 4,780 | ,070 |The accompanying notes are an integral part of these consolidated financial statements

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

FOR THE YEARS ENDED DECEMBER 31, 1999, 1998 AND 1997

<TABLE> <CAPTION>

	Common Stock		4 1 11	1 5	. 1 70		
		\$.01 Par	Addition Paid-In	al Reta Earning	ained Tota gs Stockhold	=	
	Shares	Value	Capita	•	U		
<s></s>	<c></c>	<c></c>	<c></c>	<c></c>	<c></c>		
BALANCE, December 31, 1996		4,37	8,157 \$	43,782	\$15,258,656	\$ 987,144	\$16,289,582
Stock options and warrants exercise	ed	244,	409 2	2,444	480,032	482,4	76
Tax benefit of stock options exercis	ed			290,36	51	290,361	
Net income				1,004,83	34 1,004,83	34	
BALANCE, December 31, 1997		4,62	2,566	46,226	16,029,049	1,991,978	18,067,253
Stock options and warrants issued v	vith acqui	sition		2:	36,327	236,32	7
Stock options exercised		45,250	453	88,69	6	89,149	
Tax benefit of stock options exercis	ed			64,64	4	64,644	
Net loss			(-	4,388,719	(4,388,719	)	
BALANCE, December 31, 1998		4,66	7,816	46,679	16,418,716	(2,396,741)	14,068,654
Common stock issued		53,300	533	147,9	05	148,438	

Stock warrants issued, net of issuance costs Stock options and warrants exercised Net loss	206,011 206,011 52,249 522 36,610 37,132 (814,112) (814,112)
BALANCE, December 31, 1999	4,773,365 \$ 47,734 \$16,809,242 \$(3,210,853) \$13,646,123

	The accompanying notes are an integ these consolidated financial statem	
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BOSTON BIOMEDICA, INC. AN	ND SUBSIDIARIES	
CONSOLIDATED STATEMENT	TS OF CASH FLOWS	
	Years Ended December 31,	
1999		
<\$>		
CASH FLOWS FROM OPERATING ACTIVITY Net (loss) income	TIES: \$ (814,112) \$(4,388,719) \$ 1,004,834	
Adjustments to reconcile net (loss) income to	net	
cash (used in) provided by operating activitie Depreciation and amortization	1.578.731 1.280.049 858.434	
Provision for doubtful accounts	96,661 154,335 174,925	
Deferred rent and other Deferred income taxes	(264,549) 117,911 (71,381) (447,420) (528,676) 2,391	
Tax benefit of stock options exercised	(447,420) (528,676) 2,391  64,644 290,361	
Acquired research and development	4,230,812	
Changes in operating assets and liabilities:	(45( 20() ) (655 151) (1 007 412)	
Accounts receivable Other assets	(456,286) (675,171) (1,907,413)  (13,930)	
	(228,148) (786,947) (640,301)	
Prepaid expenses and other	135,630 (144,199) 2,546	
Accounts payable	182,773 105,122 797,690	
Deferred revenue	250,490 (86,054) (102,199) (690,760) (558,264) 330,855	
Net cash (used in) provided by operating acti	vities (656,990) (1,215,157) 726,812	
CASH FLOWS FOR INVESTING ACTIVITIE	7S.	
Acquired research and development	(850,000) nent (2,727,816) (2,929,568) (2,612,697)	
Payments for additions to property and equipm	nent (2,727,816) (2,929,568) (2,612,697)	
Purchase of intangible assets  Return of denosits and other	(3,4/0) (39,625) (2,724) 27,731	
Purchase of long term investment	(750,000)	
Purchase of intangible assets Return of deposits and other Purchase of long term investment Acquisitions, net of cash aquired	(1,706,540) (1,993,722)	
Net cash used in investing activities	(2,730,540) (5,461,847) (5,396,044)	
CASH FLOWS FROM FINANCING ACTIVIT	TIES:	
Repayments of long-term debt	(11,533)  $(14,878)$   $(1,123,526)$	
	stock warrants 391,581 89,149 482,476	
	vities 3,555,475 4,051,622 (641,050)	
	ASH EQUIVALENTS: 167,945 (2,625,382) (5,310,282) 146,978 2,772,360 8,082,642	
~	**\*** • • • • • • • • • • • • • • • • • • •	
\$ 314,923

\$ 146,978

\$ 2,772,360

Cash and cash equivalents, end of year

Income taxes paid \$ 33,391 \$ 113,287 \$ 662,304
Interest paid \$ 414,297 \$ 72,755 \$ 5,731
Long-term investment included in acquisition \$ 1,482,500

</TABLE>

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

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#### 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. The Company also invests in new technologies related to infectious diseases. The Company is subject to risks common to companies in the biotechnology, medical device and diagnostic industries, including but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with governmental regulations.

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

## (i) Principles of Consolidation

The consolidated financial statements include the accounts of BBI and its wholly-owned subsidiaries, BBI Biotech Research Laboratories, Inc. ("BBI Biotech"), BBI Clinical Laboratories, Inc. ("BBICL"), BBI Source Scientific, Inc. ("BBI Source"), and BBI BioSeq, Inc. ("BBI BioSeq"). BBI consists primarily of the Diagnostic Products segment as well as executive corporate officers. During the year, the Company incorporated Panacos Pharmaceuticals, Inc., ("Panacos"). Effective January 2000, Panacos will be accounted for as an additional consolidated subsidiary of the Company. All significant intercompany accounts and transactions have been eliminated in the consolidation. Certain amounts included in the prior year's financial statements may have been reclassified to conform to the current presentation.

# (ii) Use of Estimates

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

The valuation methodology applied to the acquisition of BioSeq, Inc. (see Note 2) was based on estimated discounted future cash flows. The purchase price accounting is based on this valuation. Significant assumptions include gross and operating profit margins, and future tax, discount, and royalty rates.

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

## (iii) Revenue Recognition

Product revenue is recognized upon shipment of the products or, for specific orders at the request of the customer, on a bill and hold basis after completion of manufacture. All bill and hold transactions meet specified revenue recognition criteria which include normal billing, credit and payment terms, firm commitment and transfer to the customers of all risks and rewards of

ownership. Total revenue related to bill and hold transactions was approximately \$1,998,000, \$1,388,000, and \$459,000 for the years ended December 31, 1999, 1998, and 1997, respectively.

Services are recognized as revenue upon completion of tests for specialty 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. Billing under long-term contracts are generally at cost plus a predetermined profit. Billing occurs as costs associated with time and materials are incurred. Customers are obligated to pay for such services, when billed, and payments are non-refundable. On occasion certain customers make advance payments that are deferred until revenue recognition is appropriate. The Company does not believe there are any material collectability issues associated with these receivables.

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#### BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## (1) Business and Significant Accounting Policies (Continued)

Total revenue related to long-term contracts was approximately \$4,457,000, \$4,175,000, and \$3,125,000 for the years ended December 31, 1999, 1998 and 1997, respectively. Total contract costs associated with these agreements were approximately \$4,323,000, \$3,950,000, and \$2,782,000 for the years ended December 1999, 1998 and 1997, respectively. Included in the revenue recognized under long-term contracts are certain unbilled receivables representing additional indirect costs, which are allowed under the terms of the respective contracts. Unbilled receivables were less than \$40,000 for all years presented.

# (iv) Cash and cash equivalents

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

## (v) Research and Development Costs

Research and development costs are expensed as incurred.

#### (vi) Inventories

Inventories are stated at the lower of cost or net realizable value and include material, labor and manufacturing overhead.

# (vii) Property and Equipment

Property and equipment are stated at cost. For financial reporting purposes, depreciation is recognized using accelerated and straight-line methods, 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.

In March of 1998, the American Institute of Certified Public Accountants issued Statement of Position ("SOP") 98-1, "Accounting for the Costs

of Computer Software Developed or Obtained for Internal Use". SOP 98-1 requires computer software costs associated with internal use software to be charged to operations as incurred until certain capitalization criteria are met. SOP 98-1 is effective beginning January 1, 1999. The Company adopted this policy during 1999 as it implemented enterprise resource planning systems at two of its locations. See Footnote 4 for further information.

#### (viii) Goodwill and Intangibles

The Company has classified as goodwill, the cost in excess of fair value of the assets of the business acquired. Goodwill is being amortized on a straight-line basis over ten to fifteen years. Other intangibles primarily consist of patents, licenses, and intellectual property rights and are amortized over periods ranging from four to sixteen years.

# (ix) Impairment of Long-Lived Assets

The Company evaluates the potential impairment of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. At the occurrence of a certain event or change in circumstances, the Company evaluates the potential impairment of an asset based on estimated future undiscounted cash flows. In the event impairment exists, the Company will measure the amount of such impairment based on the present value of estimated future cash flows using a discount rate commensurate with the risks involved. Based on management's assessment as of December 31, 1999, the Company has determined that no impairment of long-lived assets exists. Upon the occurrence of a material circumstance, such as the failure of certain technology to demonstrate promise that it may gain commercial acceptance or the failure of a business segment to achieve certain performance objectives, management will reassess the value of associated assets and if appropriate at that time, will recognize an impairment charge. The realizability of the goodwill related to the

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# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# (1) Business and Significant Accounting Policies (Continued)

acquisition of BBI Source Scientific has been a specific area of focus by the Company. Management feels that although the business unit has realized operating losses since the acquisition in July 1997, the goodwill is not impaired as management believes the segment will be profitable by the end of 2001.

#### (x) Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred taxes arise from temporary differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance is provided for net deferred tax assets if, based on the weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Tax credits are recognized when realized using the flow through method of accounting. At December 31, 1999, the Company's entire valuation allowance related to the net operating losses acquired in connection with the BioSeq acquisition.

Management feels that no additional valuation allowance is required as its tax strategies and normal profitability levels will allow it to realize all of its tax assets, including federal and state net operating losses and tax credits.

# (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 in federally chartered banks, each of which is insured up to \$100,000 by the Federal Deposit Insurance Corporation. The Company limits credit risk in cash equivalents by investing only in short-term, investment grade securities including money market funds restricted to such securities. Concentration of credit risk with respect to

accounts receivable is limited to certain customers to whom the Company makes substantial sales (see Note 6). The Company does not require collateral from its customers. To reduce risk, the Company routinely assesses the financial strength of its customers and, as a consequence, believes that its trade accounts receivable credit risk exposure is limited.

#### (xii) Deferred Revenue

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

#### (xiii) Computation of Earnings per Share

Basic earnings per share is computed by dividing income available to common shareholders by the weighted average number of common shares outstanding. Diluted earnings per share is computed by dividing income 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 were antidilutive were excluded from the calculation.

#### (xiv) Segment Reporting

The Company adopted SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information," on December 31, 1998. SFAS No. 131 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. SFAS No. 131 supersedes SFAS No. 14, Financial Reporting for Segments of a Business Enterprise, but retains the requirements to report information about major customers. Disclosures required by this new standard are included in the notes to the consolidated financial statements under the caption "Segment Reporting and Related Information."

# (xv) Recent Accounting Standards

Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities" (SFAS 133)is effective, as amended for quarters of fiscal years beginning after June 15, 2000. The new standard requires companies to record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivatives and whether they qualify for hedge accounting. The key criterion for hedge

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#### BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (1) Business and Significant Accounting Policies (Continued)

accounting is that the hedging relationship must be highly effective in achieving offsetting changes in fair value or cash flows. The Company does not currently engage in derivative trading or hedging activity.

In December 1999, the Staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). This SAB summarizes certain of the Staff's views in applying generally accepted accounting principles, in the United States, to revenue recognition in financial statements. SAB 101 is effective for the Company's quarter ended June 30, 2000. The Company does not expect the provisions of SAB 101 to have a material impact on its financial statements

#### (2) Acquisition of BioSeq, Inc.

On September 30, 1998 the Company acquired the remaining common stock

outstanding of BioSeq (approximately 81%) for \$879,000 in cash (net of cash acquired of \$121,000), warrants to purchase 100,000 shares of the Company's stock at an exercise price of \$2.50 per share, minimum long-term royalty payments of \$424,000, debt and accrued interest owed by BioSeq at the time of acquisition of approximately \$736,000, and other acquisition costs. The Company also exchanged BioSeq's stock options for 46,623 BBI stock options with an average exercise price of \$2.74. Accordingly, the Company's aggregate cost of acquiring all of BioSeq's equity, including the original 19% investment under the 1996 Purchase Agreement of \$1,482,000 (classified as long-term investment at December 31, 1997 was approximately \$4,226,000. The cash portion of the acquisition was financed from a combination of debt and cash. The acquisition has been recorded using purchase accounting, and BioSeq's results are included in the consolidated results of the Company commencing October 1, 1998.

BBI BioSeq is a development stage company with patent pending technology based on pressure cycling technology. The assets were capitalized by allocating the aggregate cost of \$4,226,000 ratably to the individual components of the \$11,124,000 total estimated fair value of the assets acquired, based upon independent valuation of the assets acquired as performed by the Michel/Shaked Group, a division of Back Bay Management Company. Management believes that because of the Company's initial investment in BioSeq, and intimate knowledge of its technology and business, its understanding of the industry to which pressure cycling technology would be applied, and as a result of lengthy and intense negotiations, the Company was successful in reaching an extremely favorable purchase price for BioSeq compared to the fair value of the assets acquired.

The assets acquired and their allocation are as follows

<TABLE> <CAPTION>

ITEM	ESTIMATED ALLOCATED USEFUL LIFE FAIR VALUE PURCHASE PRICE
<s></s>	<c> <c> <c></c></c></c>
Acquired In-pr	rocess
Research & de	evelopment - \$8,764,000 \$3,381,000
Patents	16 years 2,017,000 778,000
Other assets	3 to 10 years 343,000 67,000
Totals	\$11,124,000 \$4,226,000

  |Allocated in-process research and development consists of two projects, that were on-going at the time of the acquisition: nucleic acid extraction and purification and pathogen inactivation. BioSeq had expended approximately \$1.6 million prior to September 30, 1998 on these projects. Both of these projects have encouraging preliminary data demonstrating potential feasibility, but significant scientific, mechanical and design issues remain. The Company estimates that it will spend in excess of \$4.8 million through the year 2002 to complete the development into commercially viable products and to begin generating revenue. Remaining development efforts are focused on feasibility studies to establish the key performance parameters and biological activities to be retained; designing and building a prototype instrument; further development of the prototype for the applications; scale-up of design; data generation and clinical trials; applying and obtaining Food and Drug Administration approval, where applicable, final design modifications; and transfer to manufacturing. In addition to the risk of the technology ultimately not working, failure to complete on a timely basis could allow new or existing competing technologies to be developed and commercially accepted.

The valuation methodology was based on estimated discounted future cash flows. Significant assumptions include gross and operating profit margins, and future tax, discount, and royalty rates. Recent accounting guidelines on valuation methodologies for in-process research and development are still evolving and the amount written off maybe subject to adjustment.

#### BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (2) Acquisition of BioSeq, Inc. (Continued)

The following unaudited pro forma information combines the consolidated results of operations of the Company and BioSeq as if the acquisition had occurred at the beginning of 1997, after giving effect to certain adjustments, including amortization of the intangible assets, increased interest expense on the acquisition debt, and related income tax effects. The unaudited pro forma information is shown for comparative purposes only and is based on management's estimates of research and development expenditures.

<TABLE> <CAPTION>

	Years Ende	d Decemb	per 31,
	1998 Pro Forma	1997	rma
~C\			Ша
<s> Revenues</s>	26,081,0	~C> 77 22	2,299,337
Operating income (loss)	(1,4	74,694)	191,952
Net income (loss)	(989,	327)	242,834
EPS	(0.21)	0.0	5

  |  |  |The pro forma information excludes acquired research and development of \$4,231,000

# (3) Inventories

The Company purchases human plasma and serum from various private and commercial blood banks. Upon receipt, such purchases generally undergo comprehensive testing, and associated costs are included in the value of raw materials. Most plasma is manufactured into Basematrix and other diagnostic components to customer specifications. Plasma and serum with the desired antibodies or antigens are sold or manufactured into QC Panels, Accurun(R) Run Controls, and reagents ("Finished Goods"). Panels and reagents are unique to specific donors and/or collection periods, and require substantial time to characterize and manufacture due to stringent technical specifications. Panels play an important role in diagnostic test kit development, licensure and quality control. Panels are manufactured in quantities sufficient to meet expected user demand, which may exceed one year. Inventory also includes component parts used in the manufacture of laboratory instrumentation. Inventory balances at December 31, 1999 and 1998 consisted of the following:

<TABLE> <CAPTION> 1999 1998  $\langle S \rangle$ <C> Raw materials ...... \$2,675,735 \$2,407,154 Work-in-process ..... 1,845,778 1,788,399 Finished goods ...... 2,396,403 2,494,215 \$6,917,916 \$6,689,768 </TABLE>

# (4) Property and Equipment

Property and equipment at December 31, 1999 and 1998 consisted of the following:

<TABLE> <CAPTION> 1999 1998

<s> <c< th=""><th><b>'</b>&gt;</th><th><c></c></th><th></th><th></th></c<></s>	<b>'</b> >	<c></c>		
Laboratory and manufacturing equ	ipment	\$ 3,43	56,410	\$ 3,082,834
Management information systems		3,691,3	338	2,556,193
Office equipment	1,051	,673	821,53	88
Automobiles	318,24	42	206,693	
Leasehold improvements	2,	177,236	1,61	0,260
Land, building and improvements		2,611,7	33 2	2,307,039
13,3	06,632	10,584	,557	
Less accumulated depreciation	5	5,011,608	3,6	559,134
Net book value	\$ 8,295,	,024 \$	6,925,4	23
===		= ===		===

  |  |  |  |-42-

# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# (4) Property and Equipment (Continued)

Depreciation expense for the years ended December 31, 1999, 1998 and 1997 was approximately \$1,359,000, \$1,096,000, and \$731,000 respectively. Included in 1999, 1998 and 1997 land, building and improvements is approximately \$203,000, \$1,345,000 and \$920,000, respectively, of construction in progress.

In accordance with SOP 98-1, the Company capitalized approximately \$448,000 of internal labor and related costs, in 1999, in connection with its ERP System Implementation. These costs are included in the Management Information Systems line item and are being depreciated over the same life as the system, 5 years. Depreciation expense, related to these capitalized costs was approximately \$7,000 for the year ended December 31, 1999.

# (5) Intangible Assets

Intangible assets at December 31, 1999 and 1998 consisted of the following:

<TABLE> <CAPTION>

CAPTION/			
	1999	1998	
<s></s>	<c></c>	<c></c>	
Goodwill	\$2,293,04	45 \$2,29	3,045
Patents	795,880	796,38	0
Licenses	37,752	37,75	2
	3,126,677	3,127,177	
Less accumulated amort	ization	537,367	317,352
Net book value	\$2,589.	310 \$2,8	809,825
	=======	=====	=====

  |  |  |</TABLE>

Amortization expense for the years ended December 31, 1999, 1998 and 1997 was approximately \$220,000, \$184,000, and \$125,000 respectively.

# (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 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 has five operating segments. 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 BBI 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 Clinical Laboratory Services segment performs specialty infectious disease testing for hospitals, blood banks, doctors and other clinical laboratories, primarily in North America. The Laboratory Instrumentation segment sells diagnostic instruments primarily to the worldwide in vitro diagnostic industry on an OEM basis, and also performs in-house instrument servicing. "Other" consists of research and development in two areas: pressure cycling technology ("PCT") and drug discovery. The Company performs research in the development of PCT, with particular focus in the areas of nucleic acid purification and pathogen inactivation. The Company also conducts active research, together with Dr. K. H. Lee and collaborators at the School of Pharmacy, University of North Carolina at Chapel Hill ("UNC"), in the area of anti-HIV drug discovery, with exclusive focus on natural products and their synthetic derivatives. Finally, the "Other" segment's two R&D operations do not currently have any product or service revenue, and none is expected in the near future. Their revenue to date consists of both private and public (NIH) funding of segment research. Most of the expenditures by this segment are for R&D expenses, and general management expenses including patent costs. 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.

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

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

# (6) Segment Reporting and Related Information (Continued)

information has been prepared in accordance with the internal accounting policies of the Company, as described above.

Operating segment revenue for the years ended December 31, 1999, 1998 and 1997 were as follows:

<caption></caption>	1999	1998	1997	
<s></s>	<c></c>	<c></c>	<c></c>	>
Diagnostics	\$ 11,83	37 \$	11,277	\$ 10,655
BBI Biotech	6,29	7 5	5,355	4,188
Clinical Laboratory Service	es	9,842	7,187	7 6,024
Laboratory Instrumentation	ı	2,923	3,929	9 2,608
Other	434			
Eliminations	(2,06	2) (1	1,667)	(1,176)
Total Revenue	\$ 29,	271	\$ 26,081	\$ 22,299

</TABLE>

<TABLE>

Operating segment (loss) income for the years ended December 31, 1999, 1998 and 1997 were as follows:

# <TABLE> <CAPTION>

	1999		1998		1997				
<s></s>	<c></c>		<c></c>		<c></c>				
Diagnostics	\$	784	\$	559	\$	1,357	,		
BBI Biotech		(152)	)	67		(95)			
Clinical Laboratory Service	es		656		134		403		
Laboratory Instrumentation	1		(832)		(906)		(189)		
Other	(1,3)	345)	(5	25)	(8	34)			
Acquired research & development	opmei	nt	-	-	(4,23	1)			
Total (Loss) Income from	Oper	ations	\$ (	(889)	\$ (4	1,902)	\$	1,392	
Total (Loss) Income from	Oper	ations	\$ (	(889)	\$ (4	 1,902) 	\$	1,392	

</TABLE>

Operating segment depreciation and amortization expense for the years ended December 31, 1999, 1998 and 1997 were as follows:

<TABLE> <CAPTION>

	1999		1998		1997				
<s></s>	<c></c>		<c></c>		<c></c>				
Diagnostics	\$	537	\$	408	\$	338			
BBI Biotech		419		346		182			
Clinical Laboratory Service	es		240		217		175		
Laboratory Instrumentation	n		299		292		163		
Other	8	4	17						
 Total Depreciation and A	mortiz	ation	\$ 1,	 579	\$ 1	,280	\$	858	
=									

</TABLE>

Identifiable operating segment assets are all located in the United States, and as of December 31, 1999, 1998 and 1997 were as follows:

<TABLE> <CAPTION>

19	999	1998	1997	
<s> &lt;</s>	:C>	<c></c>	<c></c>	<b></b>
Diagnostics	\$ 13,37	75 \$ 12.	,122	\$ 14,152
BBI Biotech	4,64	3 4,2	42	2,806
Clinical Laboratory Services		3,188	2,348	1,948
Laboratory Instrumentation		3,789	4,427	4,744
Other	1,167	943		•
Total Assets	\$ 26,16	52 \$ 24,	,082	\$ 23,650
===				

</TABLE>

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# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# (6) Segment Reporting and Related Information (Continued)

Operating segment capital expenditures for the years ended December 31, 1999, 1998 and 1997 were as follows:

<TABLE> <CAPTION>

CAP HON-	1999	1998	1997	
<s></s>	<c></c>	<c></c>	<c></c>	
Diagnostics	\$ 1,3	315 \$ 1	,468 \$	1,271
BBI Biotech	9	1,2	234	877
Clinical Laboratory Service	ces	307	202	196
Laboratory Instrumentation	on	128	22	269

Other 34	•		
Total Capital Expenditures	\$ 2,728	\$ 2,930	\$ 2,613

</TABLE>

Revenue by geographic area for the years ended December 31, 1999, 1998 and 1997 are as follows:

<table></table>
<caption></caption>

	1999 1	.998 19	997
<s></s>	<c></c>	<c> ·</c>	<c></c>
United States	\$ 25,231	\$ 21,978	\$ 17,706
Europe	2,509	2,453	2,614
Pacific Rim	818	1,063	1,285
Total all others	713	587	694
Total	\$ 29,271	\$ 26,081	\$ 22,299

</TABLE>

Revenue of Product and Service classes in excess of 10% of consolidated revenue (excludes inter-segment sales) for the years ended December 31, 1999, 1998 and 1997 were as follows:

<TABLE> <CAPTION>

199	9 1998	1997	
<s> <c:< th=""><th>&gt; <c></c></th><th><c></c></th><th></th></c:<></s>	> <c></c>	<c></c>	
Quality Control Products	\$ 9,445	\$ 9,369	\$ 8,220
Clinical Laboratory Testing	9,472	6,806	5,695
Government Contracts	4,530	3,535	2,638

  |  |  |The government contract revenues are from United States government agencies, primarily the National Institutes of Health (NIH) and represent the only customer with revenue in excess of 10% of consolidated revenue.

# (7) Debt

Effective June 30, 1999, the Company entered into an amended revolving line of credit agreement (the "Amended Line") with its bank, increasing the facility to \$10 million from \$7.5 million. The Amended Line matures June 30, 2001; bears interest at the Company's option based on either the base rate plus 1/4% or LIBOR plus 2.75%; carries a facility fee of 1/4% per annum, payable quarterly; and is collateralized by substantially all of the assets of the Company, excluding real property. Borrowings under the Amended Line are limited to commercially standard percentages of accounts receivable, inventory and equipment. The Company had approximately \$456,000 available under the Amended Line as of December 31, 1999.

The Amended Line contains covenants regarding the Company's total liabilities to tangible net worth ratio, minimum debt service coverage ratio, and maximum net loss. The Amended Line further provides for restrictions on the payment of dividends, incurring additional debt, and the amount of capital expenditures.

As of December 31, 1999 the Company's debt payment requirements under its revolving line of credit were \$0, \$7,145,651, \$0, \$0 and \$0 for the years ended December 31, 2000, 2001, 2002, 2003, and 2004, respectively.

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BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company's outstanding debt includes an installment note payable with an interest rate of 9.75%, due August 2001. The note is collateralized by office furniture and laboratory equipment. The Company also acquired two additional notes for automobile loans, which are both being carried at 0% financing and come due October 2002. The amounts outstanding, including the current portion, at December 31, 1999 and 1998 were \$22,414 and \$26,820, respectively.

# (8) Other Liabilities

The Company's California and Maryland facility's leases include scheduled base rent increases over the term of the lease. The amount of base rent payments is charged to expense using the straight-line method over the term of the lease. As of December 31, 1999 and 1998, the Company has recorded a long-term liability of \$326,184 and \$273,290, respectively (\$361,413 and \$308,519 including the current portion) to reflect the excess of rent expense over cash payments since inception of the lease. In addition to base rent, the Company pays a monthly allocation of the operating expenses and real estate taxes for the California and Maryland facilities.

Included in long-term liabilities at December 31, 1999 and 1998 are the present value of future minimum royalty payments of approximately \$139,000 and \$424,000 payable to the former owners of BioSeq, Inc. (See Note 2).

#### (9) Accrued Compensation

Accrued compensation consists of the following:

<TABLE> <CAPTION> Year Ended December 31 1999 1998 <S> <C> <C> Accrued payroll \$ 253,594 \$ 598,937 Accrued vacation 447,534 360,509 Accrued commissions 305,423 177,691 Other accrued compensation 182,589 147,025 1,189,140 1,284,162

</TABLE>

</TABLE>

# (10) Income Taxes

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

<TABLE> <CAPTION> 1999 1998 1997 <S> <C> <C> <C> Current (benefit) provision: federal \$(226,368) \$ (63,868) \$ 567,373 Current provision: state \$ 85,575 \$ 28,145 \$ 100,125 Total current (benefit) provision (140,793)(35,723)667,498 (5,078)Deferred (benefit) provision: federal (236,040)(417,315)Deferred (benefit) provision: state (122,139)(111,361)7,469 Total deferred (benefit) provision (358,179)(528,676)2,391 Total (benefit) provision for income taxes \$(498,972) \$(564,399) \$ 669,889

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#### (10) Income Taxes (Continued)

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

<table></table>				
<caption></caption>				
	1999	1998		
<\$>	<c></c>	<c></c>		
Current deferred taxes:				
Inventory	\$ 174,	,338 \$	169,79	96
Accounts receivable allowance		298,271	-	224,240
Technology licensed		299,883	32	2,516
Other accruals		2,298		
Total current deferred tax assets		934,790		847,268
Long term deferred taxes:				
Accelerated tax depreciation		(335,880)	(	(279,358)
Goodwill and intangibles		19,961	1	7,729
Tax credits	252,	589 6	50,000	)
Operating loss carryforwards		1,082,665		861,066
Less: valuation allowance		(798,800)	(	798,800)
Total long term deferred tax assets (li-	abilities), ne	et 220,	,535	(139,363)
Total net deferred tax assets	\$	1,155,325	\$	707,905

</TABLE>

On December 31, 1999 and 1998, operating loss carryforwards were partially offset by a valuation allowance of \$798,800. This allowance is to reserve for the entire loss carryforward obtained through the acquisition of BioSeq, Inc. The Company establishes valuation allowances in accordance with the provisions of SFAS 109 "Accounting for Income Taxes". The Company continually reviews the adequacy of the valuation allowance. The state net operating loss carryforwards expire at various dates beginning in 2002 through 2019. As of December 31, 1999, the Company had approximately \$47,000 of alternative minimum tax credits, which do not expire and approximately \$205,000 of federal research credits, which expire from 2012 through 2020. The Company has determined that no additional valuation allowance is required. This conclusion is based on its ability and intent to discontinue its operating loss position, not only for the consolidated entity, but also for each of its operating segments. If circumstances occur that change managements view about its ability to return to profitability, and utilize the net operating losses and deferred tax assets, it will re-evaluate its position with respect to valuation allowances.

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

<TABLE> <CAPTION> 1998 <S><C> <C> <C> (34%) (34%) Federal tax (benefit) provision rate 34% State tax (benefit) provision, net of federal benefit 6% (6%)(1%)23% Nondeductable writeoff of acquired research and development Other items, net 1% Effective income tax (benefit) provision rate (38%) (11%) </TABLE>

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#### BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company leases certain office space, laboratory, research and manufacturing facilities under operating leases with various terms through October 2007. All of the real estate leases include renewal options at either market or increasing levels of rent.

Rent expense for the years ended December 31, 1999, 1998 and 1997 was approximately \$1,218,000, \$914,000, and \$506,000, respectively. At December 31, 1999, the remaining fixed lease commitment was as follows:

<TABLE> <CAPTION>

CAI HOW	
Year Ended	Amount
<s></s>	<c></c>
2000	1,168,617
2001	1,106,646
2002	846,256
2003	864,470
2004	889,687
2005 and thereafter	2,372,466
	\$7,248,142

</TABLE>

In April 1999, the Company increased it's commitment to directly support a drug discovery program at UNC, in which a full-time post-doctoral research scientist and two doctoral students are working to develop synthetic derivatives of anti-HIV compounds that have been discovered pursuant to the Company's joint collaboration with UNC. The Company is committed to pay approximately \$44,000 per quarter for three years. These costs are being charged to research and development expense. Under this agreement, the Company will also have the rights to any new anti-HIV compounds and derivatives developed in the course of this sponsored research, provided the Company obtains certain regulatory approvals from the FDA. Effective January 2000, all rights and obligations under this agreement were transferred to Panacos Pharmaceuticals, Inc.

# (12) 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. To date, no such contributions have been made. During 1999, 1998 and 1997 the Company recognized administrative expense of approximately \$30,000, \$32,000, and \$23,000, respectively in connection with the plan.

# (13) Stockholders' Equity

#### Common Stock

In July 1999, the Company's Board of Directors approved the 1999 Employee Stock Purchase Plan. The Company adopted this plan, which allows eligible employees to purchase shares of the Company's stock at 85% of market value as determined at the beginning and the end of the offering period. A total of 250,000 shares have been reserved for this plan. As of December 31, 1999 no shares were issued under this plan.

# Options and Warrants

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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (13) Stockholders' Equity-(Continued)

Qualified Stock Option Plan, and designated 500,000 shares for distribution under this plan. The exercise price of an option generally equals the fair market value of the stock at grant date. Generally, options become exercisable at the rate of 25% at the end of each of the four years following the anniversary of the grant. Options expire ten years from the date of grant, or 30 days from the date the grantee's affiliation with the Company terminates.

At December 31, 1999, 1,999,500 shares were reserved for incentive stock options, of which 1,328,624 are available for future grants. At December 31, 1998, 749,500 shares have been reserved for incentive stock options, of which 179,887 are available for future grants. At December 31, 1999, 1,098,680 shares were reserved under the nonqualified stock option plan of which 489,951 were available for future grants. As of December 31, 1998, 605,929 shares were reserved for the non-qualified stock option plan of which no shares were available for future grants.

In August 1999, the Company sold 500,000 warrants to purchase the Company's stock to Paradigm Group, a private investment company. The private placement consisted of 400,000 common stock purchase warrants with a exercise price of \$4.25 and 100,000 common stock purchase warrants with an exercise price of \$5.25. Paradigm Group paid the Company \$50,000 for the warrants. In addition, National Securities received 40,000 common stock purchase warrants with an exercise price of \$4.25, 10,000 common stock purchase warrants with an exercise price of \$5.25, and 25,000 common stock purchase warrants with an exercise price of \$8.00, as transaction fee.

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

On December 11, 1998, the Company's Board of Directors authorized the Company to offer a reduction of the stock option exercise price to \$3.25 per share, which represented a premium over the market price of \$2.56 on that day. Any option holder with outstanding stock options with an exercise price higher than \$3.25 was eligible to participate in the repricing. A total of 411,417 options were repriced, which represents substantially all eligible options. The original vesting schedule, generally four years from date of grant, remained unchanged. However, all optionees accepting the offer agreed not to exercise vested, repriced options for a period of one year from the date of amendment. The previous weighted average exercise price of the options repriced was \$6.72.

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 1999, 1998 and 1997. The minimum value option pricing model was used for all grants during, and prior to, 1996 as they were granted prior to the Company's IPO.

<tab< th=""><th>LE&gt;</th><th></th><th></th><th></th><th></th><th></th></tab<>	LE>					
<cap< td=""><td>TION&gt;</td><td></td><td></td><td></td><td></td><td></td></cap<>	TION>					
		1999	1	998	1997	
	-					-
<s></s>		<c></c>	>	<c></c>	<c></c>	
	Risk-free interest rate		5.26%		4.69%	5.72%
	Volatility factor		76.68%		75.57%	55.00%
	Weighted average expect	ed life	5.1 y	ears	5.0 years	5.0 years
	Expected dividend yield		0		0	0

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,

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# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (13) Stockholders' Equity-(Continued)

the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

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

<table></table>
<caption></caption>

		1999	1998	1997	
<s></s>		<c></c>	<c></c>	<c></c>	
	Net (loss) income-as reported		\$(814,112)	\$(4,388,719)	\$1,004,834
	Net (loss) income-pro forma		\$(1,394,564)	\$(4,776,812)	851,408
	Net (loss) income per share-as r	reported, basi	ic $(.17)$	(.94)	.23
	Net (loss) income per share-as r	eported, dilu	ited $(.17)$	(.94)	.21
	Net (loss) income per share-pro	forma, basic	(.30)	(1.03)	.19
	Net (loss) income per share-pro	forma, dilut	ed $(.30)$	(1.03)	.18
<td>ABLE&gt;</td> <td></td> <td></td> <td></td> <td></td>	ABLE>				

Because SFAS 123 provides for pro forma expense for options granted beginning in 1995, the pro forma expense will likely increase in future years as new option grants become subject to the pricing model. The average fair value of options granted during 1999, 1998 and 1997 is estimated as \$2.63, \$1.77 and \$4.44, respectively.

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# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# (13) Stockholders' Equity-(Continued)

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

<TABLE> <CAPTION>

	Stock Options		Warrants				
	Weighted Average price		Weighted Average price		Total		
	Shares pe	r share Sh	ares pe	er share	Shares	Exercisable	
<s></s>	<c></c>	<c> &lt;</c>	C>	<c></c>	<c></c>	<c></c>	
Balance outstanding, Decemb	er 31, 1996	917,887	3.10	280,0	7.6	3 1,197,887	839,272
Granted	263,050	7.42			263,050		
Exercised	(124,409)	1.44	(120,000)	2.5	0 (244,4	409)	
Expired	(30,435)	7.36			(30,435)		
Balance outstanding, Decemb	er 31, 1997	1,026,093	4.28	160,0	- 000 11.	48 1,186,093	832,231

Granted	358,836	3.80 *	100,000	2.50	458,836		
Exercised	(45,250)	1.97		(4:	5,250)		
Expired	(165,013)	6.05		(16	5,013)		
Balance outstanding,	December 31, 1998	1,174,666	2.75 **	260,000	8.34	1,434,666	829,434
Granted	260,500	3.91	579,153	4.73	839,653		
Exercised	(47,249)	0.52	(5,000)	2.50	(52,249)		
Expired	(107,688)	3.56		(10	7,688)		
Balance outstanding,	December 31, 1999	1,280,229	3.00	834,153	5.80	2,114,382	1,591,795
				_			

</TABLE>

The following table summarizes information concerning options outstanding and exercisable as of December 31, 1999:

<TABLE> <CAPTION>

		Options Outstanding			Options I	e	
Weighted Average Remaining Range of Exercise Prices Li			Weighted Number of Average ife Options Exercise		Weighted Number of se Price Options		Average Exercise Price
<s></s>	<c></c>	<c></c>		 :C>	<c></c>	< <c></c>	
0.00-1.70	1.20	184.33		\$ 1.5062	184.334	•	1.5062
1.71-2.55	2.80	189,76		\$ 2.5000	189,76	•	2.5000
2.56-3.25	6.80	746,37	<sup>7</sup> 8	\$ 3.2054	380,54	1 \$	3.1925
3.26-4.25	9.60	131,75	50	\$ 4.2500		\$ 0.0	0000
4.26-5.10	9.00	28,000	0	\$ 4.6563	3,000	\$ 4	.5000
	1	,280,229	_	757,6	542		
			=	==			

</TABLE>

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# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# (14) Computation of Net Income per Share

The following illustrates the computation of basic and diluted net income per share.

<TABLE> <CAPTION>

<caption></caption>	Ye					
-	1999	1998	3	1997		
<s></s>	<c></c>	<c></c>		<c></c>		
Shares, basic	4,66	9,717	4,654	,609	4,437,8	301
Net effect of dilutive common equivalents-based on treasury method using average market	stock				342,	269
Shares, diluted	4,6	69,717 ====	4,654	1,609	4,780,	070
Net (loss) income, basic and di	luted	\$ (814	,112)	\$(4,38	8,719) ====	\$ 1,004,834
Net (loss) income per share-ba	sic	(0.1	7)	(0.94)	)	0.23

<sup>\*</sup> Includes 46,623 shares at \$2.74 granted in connection with the BioSeq, Inc. acquisition.

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

0.21

\* Potentially dilutive securities of 68,023 and 192,826 were not included in the computation of diluted earnings per share because to do so would have been antidilutive for twelve months ended December 31, 1999 and 1998.

# (15) Selected Quarterly Financial Data (Unaudited)

Unaudited (Amounts in thousands, except for per share data)

<table></table>				
<caption></caption>				
1999	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
<s></s>	<c></c>	<c></c>	<c></c>	<c></c>
Total revenue	\$ 6,845	\$ 7,139	\$ 7,480	\$ 7,807
Gross profit	2,566	2,675	2,905	2,689
Net (loss)	(237)	(225)	(257)	(96)
Net (loss) per share, basic	(0.05	(0.05)	(0.05)	(0.02)
Net (loss) per share, diluted	(0.05	(0.05)	(0.05)	(0.02)
<caption></caption>				
1998	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
				<b></b>
<s></s>	<c></c>	<c></c>	<c></c>	<c></c>
Total revenue	\$ 6,273	\$ 6,383	\$ 6,181	\$ 7,244
Gross profit	2,178	2,709	2,448	2,669
Net (loss) income	(645)	134	(3,377)	(502)
Net (loss) income per share, ba	asic (0	0.14) 0.	03 (0.7	72) (0.11)
Net (loss) income per share, di	iluted (	0.14) 0	.03 (0.	72) (0.11)

  |  |  |  |-52-

# Report of Independent Accountants

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

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Boston Biomedica, Inc. and its subsidiaries (the "Company") at December 31, 1999 and 1998, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 1999 in conformity with accounting principles generally accepted in the United States. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and 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, 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 the opinion expressed above.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts February 29, 2000

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

None.

#### PART III

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

The information called for by Item 10 is hereby incorporated by reference to the information under Part I, Item 1 - Business under the heading "Executive Officers of the Registrant" at page [18] of this report, and to the information in the registrant's definitive proxy statement, which is expected to be filed by the registrant within 120 days after the close of its fiscal year.

#### ITEM 11. EXECUTIVE COMPENSATION

The following summary compensation table sets forth the compensation of the Company's Chief Executive Officer and each of the Company's four most highly compensated other executive officers who were serving as executive officers of the Company at the end of fiscal year 1999 (collectively, the "Named Executive Officers").

**Summary Compensation Table** 

<TABLE> <CAPTION>

Annual Compensation Compensation

Fiscal Other Annual All Other Salary Stock Options Name and Bonus Compensation Compensation Year Principal Position Ended (\$) \$ (#) (\$) (\$) <S><C> <C> <C> <C> <C> <C> Richard T. Schumacher, 12/31/99 25,000 \$229,010 \$1,520(1) \$184,450(2)(4) Chief Executive Officer 12/31/98 200,002 \$5,000 370(1) 15,000 420(2) and Chairman of the Board 12/31/97 194,616 1,588(1) 420(2) Kevin W. Quinlan, 12/31/99 17,500 \$168,075 President, Chief 12/31/98 143,347 \$4,000 10,000 Operating Officer and 12/31/97 139,927 Director Barry M. Warren 12/31/99 \$147,547 10,000 Senior Vice President and 12/31/98 137,601 \$3,000 6,000 General Manager 12/31/97 129,367 Richard C. Tilton, Ph.D. 12/31/99 \$135,203 \$6,000(3) \$3,000 6,000 Senior Vice President, 12/31/98 127,019 6,000(3)Science and Technology 12/31/97 121,164 6,000(3)Mark M. Manak, Ph.D. 12/31/99 \$129,894 6,000 \$3,000 Senior Vice President and 12/31/98 118,510 General Manager 12/31/97 116,388 </TABLE>

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<sup>(1)</sup> Consists of personal usage of Company vehicle

<sup>(2)</sup> Includes the value of premiums paid for a term life insurance policy.

<sup>(3)</sup> Consists of automobile allowance

<sup>(4)</sup> Consists of exercise of options

# <TABLE> <CAPTION>

CHI HOIV	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock				
	Number of Securities Underlyin	s Option	s I	Exercis	se 			opreciation n Term at Ye	ear End
Name	Options Gran	Employe ted 199		Price (\$/S		Expirate Date		10%	
<s></s>	<c></c>	<c></c>		<c></c>	<	C>	<c></c>	<c></c>	
Richard T. Schuma	acher	25,000	9.6	0%	4.6	75	07/27/09	56,195	158,710
Kevin W. Quinlan		17,500	6.72%	0	4.25	(	7/27/09	46,774	118,535
Barry M. Warren		10,000	3.84%	)	4.25	0	7/27/09	26,728	67,734
Richard C. Tilton,	Ph.D.								
Mark M. Manak, P									

 h.D. |  |  | - | - |  |  |  |  |The following table shows stock options exercised by the Named Executive Officers during fiscal 1999, including the aggregate value realized upon exercise. This represents the excess of the fair market value over the purchase price at the time of purchase. In addition, this table includes the number of shares underlying both "exerciseable" (i.e. vested) and "unexerciseable" (i.e. unvested) stock options as of December 31, 1999. Also reported are the values of "in-the-money" options, which 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 \$2.875.

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

# <TABLE> <CAPTION>

			Num	ber of Securi	ties	Value of	Unexercised	
	Shares		Un	derlying Une	exercised	In-th	e-Money Opt	ions
	Acquired	1	(	Options at Ye	ar End	at \	Year End	
	on	Value (1	)					
Name	Exerc	cise Re	alized	Exercisabl	e Unexero	eisable	Exercisable	Unexercisable
<s></s>	<c></c>	<c></c>		<c></c>	<c></c>	<c></c>	<c></c>	
Richard T. Schuma	cher	40,000	\$180	0,000	98,690	38,690	\$103,82	7 \$164
Kevin W. Quinlan,				71,250	26,25	0 \$44	4,375	
Barry M. Warren				33,375	20,125	5 -		
Richard C. Tilton,	Ph.D.			38,375	5,12	25		
Mark M. Manak, P	h.D.			38,37	5 10,	125		

  |  |  |  |  |  |  |  |(1) 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.

# Compensation of Directors

Directors of the Company do not receive cash compensation for their services. Each Director has been eligible to receive options to purchase Common Stock under the Company's 1987 Non-Qualified Stock Option Plan, which expired in December 1997, and the Company's 1999 Nonqualified Stock Option Plan.

Compensation Committee Interlocks and Insider Participation

Decisions regarding executive compensation are made by the Board of Directors based on the recommendations of the Compensation Committee. The Compensation Committee of the Board of Directors is comprised of Richard T. Schumacher and Calvin A. Saravis, each of whom has received

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

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

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

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

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# PART IV

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

<table></table>	
<\$> <c></c>	
(a) 1. Index to Financial Statements:	
Consolidated Balance Sheets as of December 31, 1999 and 199831	
Consolidated Statements of Income for the three years ended December 31, 199932	
Consolidated Statements of Changes in Stockholders' Equity for the three years ended	
December 31, 199933	
Consolidated Statements of Cash Flows for the three years ended December 31, 199934	ļ
Notes to Consolidated Financial Statements	
Report of Independent Accountants50	
(a) 2. Financial Statement Schedule:	
Schedule II-Valuation and Qualifying Accounts60	

  |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)

Thiancial Statements of the Notes to Consolidated Financial Statements.					
(a) 3. Exh	ibits:				
<tables <captio="" exhib<="" td=""><td>N&gt; bit No. Reference</td><td></td></tables>	N> bit No. Reference				
<s></s>	<c> <c> <c></c></c></c>				
3.1	Amended and Restated Articles of Organization of the Company	A**			
3.2	Amended and Restated Bylaws of the Company	A**			
4.1	Specimen Certificate for Shares of the Company's Common Stock	A**			
4.2	Description of Capital Stock (contained in the Restated Articles of Organization of the Company filed as Exhibit 3.1)	A**			
4.3	Form of warrants issued in connection with Paradigm Group	H**			
10.1	Agreement, dated January 17, 1994, between Roche Molecular Systems, the Company	, Inc. and A**			
10.2	Exclusive License Agreement, dated April 28, 1999, between the Univer- North Carolina at Chapel Hill and the Company	rsity of Filed herewith			
10.3	Agreement, dated October 1, 1995, between Ajinomoto Co., Inc. and the	e Company A**			
10.4	Lease Agreement, dated July 28, 1995, for New Britain, Connecticut Facebetween MB Associates and the Company	cility A**			
10.5	1987 Non-Qualified Stock Option Plan*	A**			

	10.6	Employee Stock Option Plan*	A**		
	10.7	1999 Non-Qualified Stock Option Plan*	I**		
	10.8	1999 Employee Stock Purchase Plan*	I**		
<td colspan="5">10.9 Underwriters Warrants, each dated November 4, 1996, between the Company and each of Oscar Gruss &amp; Son Incorporated and Kaufman Bros., L.P. </td>	10.9 Underwriters Warrants, each dated November 4, 1996, between the Company and each of Oscar Gruss & Son Incorporated and Kaufman Bros., L.P.				

		-57-			
	ABLE>				
APTIO Exhib		Reference			
	10.10	-	· ·	C\*\*	
	10.11	Contract, dated March 1, 1997, between National C	Cancer Institute and the Compar	ny D\*\*	
	10.12	Lease Agreement, dated May 16, 1997, for Gaither between B.F. Saul Real Estate Investment Trust and t		E\*\*	
	10.13	Lease Agreement dated January 30, 1995 for Gard between TR Brell, Cal Corp. and Source Scientific, In Lease, dated July 2, 1997, for Garden Grove, Californ Scientific, Inc. and BBI Source Scientific	nc., and Assignment of	F\*\*	
	10.14	Contract, dated July 1, 1998, between the National the Company (NO1-A1-85341)	Institutes of Health and	G\*\*	
	10.15	Contract, dated July 1, 1998, between the National Institute and the Company (NO1-HB-87144)	Heart Lung and Blood	G\*\*	
	10.16	Line of Credit Agreement with BankBoston dated 3	June 30, 1999	H\*\*	
	10.17	Agreement with Paradigm Group for the purchase	of warrants dated August 18, 19	999 H\*\*	
	10.18	Agreement with MDBio for the purchase of commo warrants, dated September 30, 1999	on stock and common stock	Filed herewith	
	10.19	Lease Agreement dated September 30, 1999, for Fr between MIE Properties, Inc., and the Company.	rederick, Maryland facility,	Filed herewith	
	10.20	Sponsored Research Agreement with the University Carolina, Chapel Hill and the Company, dated, April		l herewith	
	10.21	Repository Contract with National Institute of Alle Infectious Disease, Division of AIDS (NO1-A1-9538		rewith	
	21.1	Subsidiaries of the registrant	Filed herewith		
	23	Consent of PricewaterhouseCoopers LLP	Filed herewit	h	
	27	Financial Data Schedule	Filed herewith		
99 ABLE	Audited Financial Statements of BioSeq, Inc., for the 1997, 1996 and for the period October 17, 1994 (Date December 31, 1997.		Filed herewith		
A Incorporated by reference to the registrant's Registration Statement on Form S-1 (Registration No. 333-10759) (the "Registration Statement"). The number set forth herein is the number of the Exhibit in said Registration Statement.					
В	B Incorporated by reference to Exhibit No. 10.17 of the Registration Statement.				
C

Statement.

Incorporated by reference to the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1996.

Incorporated by reference to the registrant's Quarterly Report on Form

- 10-Q for the fiscal quarter ended March 31, 1997.
- E Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1997.

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- F Incorporated by reference to the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.
- G Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1998.
- H Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 1999.
- I Incorporated by reference to the registrant's proxy statement, filed with the Securities and Exchange Commission on June 14, 1999.
- \* Management contract or compensatory plan or arrangement.
- \*\* In accordance with Rule 12b-32 under the Securities Exchange Act of 1934, as amended, reference is made to the documents previously filed with the Securities and Exchange Commission, which documents are hereby incorporated by reference.

# (b) REPORTS ON FORM 8-K.

The Registrant did not file any Current Reports on Form 8-K during the quarter ended December 31, 1999.

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# **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: December 7, 2000 Boston Biomedica, Inc.

By: /s/ Richard T. Schumacher Richard T. Schumacher Chief Executive Officer

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

<ta< th=""><th>BLE&gt;</th><th></th><th></th></ta<>	BLE>			
<ca< td=""><td>PTION&gt;</td><td></td><td></td></ca<>	PTION>			
	SIGNATURES	TITLES	DATE	
<s></s>		<c></c>	<c></c>	
	Richard T. Schumacher	Director and Principal Executive Officer	March 28, 2000	
	Kevin W. Quinlan	Director and Principal Accounting and Fina	March 28, 2000 ncial Officer	
		Director	March 28, 2000	
	Francis E. Capitanio			
		Director and Treasurer	March 28, 2000	
	Dr. William R. Prather, N	 ИD.		

Director March 28, 2000

Calvin A. Saravis, Ph.D. </TABLE>

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# Exhibit 23

# CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-3 (File Nos. 333-94379 and 333-46426) and S-8 (File Nos. 333-24749 and 333-30320) of Boston Biomedica, Inc. and its subsidiaries (the "Company") of our report dated February 29, 2000 relating to the financial statements and financial statement schedule, which appears in this Form 10-K/A.

/s/ PricewaterhouseCoopers LLP Boston, Massachusetts December 7, 2000

# REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Stockholders of BioSeq, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, changes in stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of BioSeq, Inc. (a development stage enterprise) at December 31, 1997 and 1996 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 1997 and for the period from October 17, 1994 (date of inception) to December 31, 1997, in conformity with accounting principles generally accepted in the United States. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States 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 the opinion expressed above.

/s/ PricewaterhouseCoopers, LLP

Boston, Massachusetts July 10, 1998, except as to certain information in the second paragraph of Note I, for which the date is September 30, 1998.