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BOSTON BIOMEDICA INC
Form 10-K/A
May 02, 2001

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

Form 10-K/A No. 1

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(Mark One)

X Annual Report Pursuant to Section 13 or 15(d) of the Securities
Exchange Act of 1934 For the fiscal year ended December 31, 2000, 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 .

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

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Massachusetts

(State or other Jurisdiction of Incorporation or Organization)

375 West Street,
West Bridgewater, Massachusetts

(Address of Principal Executive Offices)

02379-1040

(zip code)

04-2652826

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

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 X No

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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 28, 2001 was \$6,799,889, based on the closing price of the common stock as quoted on the Nasdaq National Market on that date.

As of March 12, 2001 there were 6,454,841 shares of the registrant's common stock outstanding.

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PART I

ITEM 1. BUSINESS

Boston Biomedica, Inc. and its wholly-owned subsidiaries (together, "the Company"), provide products and services for the detection and treatment of infectious diseases such as AIDS and Viral Hepatitis. As of March 1, 2001, the Company had three business units, which are comparable to operating segments (the terms "business units" and "operating segments" are used herein interchangeably):

- (1) BBI Diagnostics, an ISO 9001 certified manufacturer of quality control and other diagnostic products used to increase the accuracy of in vitro diagnostic tests;
- (2) BBI Biotech Research Laboratories, the research and development arm of the Company which supplements its support for the other BBI business units with research contracts and repository services primarily for agencies of the United States government; and
- (3) BBI Source Scientific, an ISO 9001 and EN 46001 certified manufacturer of laboratory and medical instruments.

In addition, the Company is conducting research and development in the area of Pressure Cycling Technology ("PCT") with the goals of introducing new solutions for a number of healthcare issues, including: inactivation of pathogens in human plasma, extraction of nucleic acids, food safety, and genomics.

In late 2000, the Company elected to exit the clinical laboratory segment of the business and accordingly, in February 2001, the Company sold certain assets of BBI Clinical Laboratories, a wholly-owned subsidiary, to a third party. The Company intends to complete its' exit from this segment of the business by the end of 2001.

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

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Manager is to achieve the agreed upon goals and plan of the business unit. The primary focus of corporate is to oversee the business units and guide them according to the strategic direction of the Company.

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

In October 1999, the Company formed a new, wholly-owned subsidiary, Panacos Pharmaceuticals, Inc., ("Panacos"), a Delaware corporation. All of the Company's technology related to its drug discovery and vaccine programs, consisting primarily of patents and related sponsored research agreements, were transferred to Panacos effective January 2000. In accordance with its strategic plans, Panacos obtained additional equity financing from third party investors in November 2000 in order to obtain the substantial amount of capital required to progress to more advanced stages of drug development including human clinical trials. As of December 31, 2000, the Company owns approximately 30.5% of the equity of Panacos via nonvoting shares.

The Company's strategy is to leverage its scientific capabilities in microbiology, immunology, virology, and molecular biology to (1) capitalize on both the emerging end-user market for quality control products, 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

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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.

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

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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 2000 and 1999 and the "Other" segment in fiscal 2000, 1999 and 1998. 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 20,000 individual blood units and specimens (with volumes ranging from 1 ml to 800 ml) which provides most of the raw material for its products. Within the Diagnostic Products class are two groups: Quality Control Products, consisting of Quality Control Panels and Accurun(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:

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Quality Control Panels

| Product Line | Description | Use |
|-----------------------|---|---|
| Seroconversion Panels | Plasma samples collected from a single individual over a specific | Compare the clinical sensitivity of competing |

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

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

Seroconversion and performance panels are comprised of unique and rare plasma specimens obtained from individuals during the short period of time when the markers for a particular disease are converting from negative to positive. As a result, the quantity of any such panel is limited, so that the Company must replace these panels as they sell out with another panel comprised of different specimens from a different individual, equally unique and rare. The Company believes that its inventory and relationships with blood centers affords it a competitive advantage in acquiring such plasma for replacement panels and

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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 use run controls to monitor test performance, and 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 test tube, normally used for a specimen, and will test it in the same manner that it tests the donor or patient specimens. It will then compare the results generated to an acceptable range for the run control, determined by the user, to 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 50 Accurun(R) products. Five products have been discontinued, for a total of 49 Run Controls available as of December 31, 2000. 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. 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, 2001, a total of 14 products in the Accurun 1(R) line and 27 single analyte Accurun(R) controls have either received 510(k) clearance or have been validated.

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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 and 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.

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) and MicroChemII(R) Photometers. 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.

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 proprietary 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.

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

Services

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

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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, performing tests for researchers, and development of custom nucleic acid amplification assays. Cell biology and immunology services include sterility testing, virus infectivity assays, cultivations of virus or bacteria from clinical specimens, preparation of viral or bacterial antigens and custom western blot assays.

The Company currently provides contract research services under several contracts and grants. These services are primarily related to infectious disease diagnostics, in support of the products and services that the Company wishes to develop. Current contracts include the following: clinical trials support for candidate HIV vaccines, 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. Additional assays under development include PCR based assays for Parvovirus B19, Hepatitis B virus and Erhichiosis.

Blood Processing and Repository Services

Since 1983, BBI Biotech has provided blood processing and repository services for the National Cancer Institute ("NCI"), also a part of the National Institutes of Health ("NIH"). The repository stores over 8,000,000 specimens and processes or ships up to several thousand specimens per week in support of various NIH cancer and virus research programs. In 1997, BBI Biotech was awarded a five-year (including renewal options) NCI repository contract with aggregate payments of up to \$5.2 million. In 1998, BBI Biotech received a six-year \$4.7 million repository contract (including five one-year extension options) with the National Heart, Lung and Blood Institute of the NIH. In 1999, it received a seven-year, \$9.6 million repository contract with the National Institute of Allergy and Infectious Disease. In 2000, BBI Biotech was awarded a one-year \$854,000 subcontract by New England Research Institutes, Inc. to provide repository and related specimen processing and testing services for the Hepatitis C Antiviral Long-term Treatment against Cirrhosis (HALT-C) Trial, a clinical trial funded by the National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK), an institute of the NIH. BBI Biotech is currently focusing on developing a research and development program to extend the life and maintain the quality of specimens that are stored at ultra-low temperatures as well as expanding the Company's repository customer base to include more industry clients. To date all renewal options under these contracts have been approved, although the Company cannot be certain that any subsequent options

will be exercised.

Other Services

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

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

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

Research and Development

The Company's research and development effort subsequent to December 31, 2000 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 design and development of new laboratory instruments and mechanical and optical detection techniques, emphasizing its Verif-EYE reflectance reader, and (iii) the development of pressure cycling technology ("PCT") for nucleic acid purification and pathogen inactivation. The Company has approximately 20 full or part-time employees involved in its research and development effort associated with continuing operations as of December 31, 2000. As announced in 1998, at the time of its acquisition of BioSeq, Inc., the Company continues to invest significantly in research and development both in whole dollars and as a percentage of revenue in 2000, 1999 and 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."

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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 2000, the Company introduced 11 new Seroconversion, Performance, and Sensitivity Panel products, and 4 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 2000.

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 as well as an updated version of the MicroPhotometer (MicroChemII). 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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Sales and Marketing

The Company's sales and marketing efforts are organized by business unit consistent with the unit's business objectives, and coordinated via frequent planning with senior management. Overall, the Company employs approximately 24 people in sales, marketing, and customer service functions associated with continuing operations as of December 31, 2000. The Company's overall marketing strategy is to focus on the needs of its customers in two broad areas: (i) the quality and accuracy of test results in the in vitro diagnostic industry, and (ii) products and services in support of infectious disease researchers.

The strategy for Diagnostic Products is to focus on customer needs in the infectious disease testing market throughout the entire test kit life-cycle, from initial research and development, through the regulatory approval process and test kit production, to training, troubleshooting and routine use by end-users such as clinical laboratories, hospitals and blood banks. The end-user portion of this market is promoted under the marketing platform, known as "Total Quality System" ("TQS"). TQS is a package of Quality Control Products, including the Company's Accurun(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

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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(R) product line to support the high growth nucleic acid testing market, and to capitalize on the worldwide implementation of new technology to improve the safety of blood products.

The Company's Diagnostic Products are currently sold through a combination of telephone, mail, third party distributors and direct sales efforts. Domestically, Diagnostic Products are sold through a direct sales force led by a Director of Sales and Marketing. The sales force consists of two sales group managers and 12 sales representatives. Internationally, the Company distributes its Diagnostic Products both directly and through 22 independent distributors located in Japan, Australia, South America, Southeast Asia, Israel and Europe. The Company's international sales manager oversees the Company's foreign distributors. The Company's Laboratory Instruments are sold through a direct domestic and international sales force consisting of one director and one sales representative.

The Company emphasizes high quality products and services, technical knowledge, and responsiveness to customer needs in its marketing activities for both products and services. The Company educates its distributors, customers and prospective customers about its products through a series of detailed marketing brochures, technical bulletins and pamphlets, 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. In 1999 the Company introduced a new product information library on its 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. 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. 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.

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Customers

The Company's customers for Diagnostic Products consist of four major groups: (1) international diagnostics and pharmaceutical manufacturing companies, such as Abbott Diagnostics, Bayer, bioMerieux, Biorad, Chiron, Dade-Behring, DiaSorin, Fujirebio, Hoffman LaRoche, 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

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National de la Transfusion Sanguine, and the German Paul Ehrlich Institute, (3) national and international proficiency providers such as the College of American Pathologists and the European Union Concerted Action for Quality Control and (4) end-users of diagnostic test kits, such as hospital and independent clinical laboratories, including Quest Diagnostics, Specialty Laboratories, public health laboratories and blood banks, including the American Red Cross, Swiss Red Cross, and United Blood Services.

The Company's customers for Laboratory Instruments consist of international diagnostic and pharmaceutical manufacturing companies and are generally sold on an OEM basis, for use by hospitals, and clinical and research laboratories. In addition, Laboratory Instruments are sold directly to environmental and food testing laboratories, and wineries. Customers include Hitachi Chemical Diagnostics, Beckman/Hybritech Inc., Vicam, and Toray Fuji Bionics Inc. The Company's customers for contract research include various agencies of the National Institutes of Health (NIH) such as the National Institute of Allergies and Infectious Disease ("NIAIDS"), the National Cancer Institute ("NCI"), and the National Heart Lung and Blood Institute ("NHLBI").

The Company does not have long-term contracts with its customers for Diagnostic Products, which are generally sold pursuant to purchase orders for 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 2000, 1999, and 1998, sales (from continuing operations) to the Company's three largest customers accounted for an aggregate of approximately 20%, 24% and 24%, respectively, of the Company's net sales, although the customers were not identical in each period. During the fiscal years 2000, 1999, and 1998, the combined revenues from all branches of the National Institutes of Health, a United States Government agency, accounted for approximately 30%, 23% and 18%, respectively, of total consolidated revenues from continuing operations 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 research and development laboratory (including PCT) in Gaithersburg, Maryland and a repository facility in Frederick, Maryland. See "Item 2 -- PROPERTIES."

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Competition

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

In the area of Quality Control Products, the Company competes in the United States with NABI (formerly North American Biologicals, Inc.) in run controls and quality control panel products, with Acrometrix, 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.

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

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

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

Intellectual Property

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

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

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The Company has four patents issued and several pending patent applications for its Pressure Cycling Technology. Several of these have been followed up with foreign applications, and the Company expects to file additional foreign applications in 2000 relating to Pressure Cycling Technology. These patents expire between 2015 and 2018.

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.

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

Government Regulation

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

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

The Company's Accurun(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, 2001, a total of 14 products in the Accurun 1(R) line and 27 single analyte Accurun(R) Run controls have either received 510(k) clearance or have been validated according to the Company's protocols and are manufactured

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

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

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a set of supplementary requirements applicable to their products.

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

The Company's service-related business (clinical trials, 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") and Good Manufacturing Practice ("GMP") regulations, investigational new drug or device regulations, Institutional Review Board ("IRB") regulations and informed consent regulations.

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

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

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

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Employees

As of December 31, 2000 the Company employed 259 persons, all of whom were located in the United States. Of these, 100 persons were employed by the West Bridgewater, Massachusetts company, 68 by the New Britain, Connecticut company (a discontinued operation as of December 31, 2000), 69 at its two Maryland facilities, and 22 by the Garden Grove, California company. None of the Company's employees is covered by a collective bargaining agreement. The Company believes that it has a satisfactory relationship with its employees.

Executive Officers of the Registrant

The following table sets forth the names, ages and positions of the executive officers of the Company as of December 31, 2000:

| Name | Age | Position |
|-------------------------------|-----|---|
| Richard T. Schumacher | 50 | Chief Executive Officer and Chairman of the Board |
| Kevin W. Quinlan | 50 | President and Chief Operating Officer; and Director |
| William R. Prather, R.Ph, M.D | 53 | Senior Vice President, Finance and Business Development, Treasurer and Director |
| Patricia E. Garrett, Ph.D | 57 | Senior Vice President - Strategic Programs |
| Mark M. Manak, Ph.D | 49 | Senior Vice President and General Manager of BBI Biotech |
| David F. Petersen | 54 | Senior Vice President and General Manager of BBI Source |
| Richard C. Tilton, Ph. D | 64 | Senior Vice President, Science and Technology |
| Kathleen W. Benjamin | 44 | Vice President, Human Resources |
| Richard D'Allessandro | 54 | Vice President, Information Technology |

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

Mr. Quinlan, a Director of the Company since 1986, has served as President and Chief Operating Officer since August 1999. 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.

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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

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

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 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.

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.

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

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ITEM 2. PROPERTIES.

The Company owns its corporate offices and diagnostic products manufacturing facility for its BBI Diagnostics operating segment, which is located in a two-story, 32,000 square foot building in West Bridgewater, Massachusetts. The Company has been renovating and expanding this facility during recent years, and believes that upon completion of renovations, its facility in West Bridgewater MA will be sufficient to meet its needs for several years. This building is subject to a 10 year mortgage. Monthly payments on this mortgage is based on a 20 year amortization schedule with a balloon payment representing the remaining balance due in full on March 10, 2010. 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. Commencing in October 2000, approximately 17,000 square feet of this facility were subleased to a third party through the end of the lease term. The Company leases laboratory facilities in Gaithersburg and Frederick, Maryland. The BBI Biotech segment's Gaithersburg facility contains 36,500 square feet of custom built laboratory and office space, and is occupied under a ten-year lease that is due to expire on October 31, 2007. The Frederick facility contains 36,000 square feet of 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.

BBI Clinical Laboratories, a discontinued operation as of December 2000, occupies a 15,000 square foot facility in New Britain CT facility pursuant to a lease which expires in July 2004. In February 2001, the buyer of certain assets and liabilities of BBICL agreed to reimburse the Company for essentially all rental-related costs of this facility through December 31, 2001.

ITEM 3. LEGAL PROCEEDINGS.

On August 18, 2000, the Company received a summons and complaint from Paradigm Group, LLC naming the Company as a defendant. Paradigm Group, LLC is a selling shareholder in the Company's registration statement on Form S-3 which has been declared effective by the Securities and Exchange Commission on December 8, 2000. The suit, filed in the Circuit Court of Cook County, Illinois, alleged breach of contract claims and fraud against the Company in connection with the sale by the Company to the Paradigm Group, LLC of warrants to purchase up to 500,000 shares of the Company's common stock, the exercise of those warrants by Paradigm Group, LLC and a delay in the registration of those shares with the Securities and Exchange Commission. Paradigm Group LLC sought several remedies, including \$3,000,000 in damages or unspecified monetary damages, return of the \$42,500 purchase price for the warrants and rescission of its exercise of the warrants, and unspecified punitive damages. In December 2000, Paradigm Group, LLC withdrew this lawsuit.

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

No matter was submitted during the fourth quarter of fiscal 2000 to a vote of security holders of the Company.

PART II

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

The Company's Common Stock, \$.01 par value, (the "Common Stock") on October 31, 1996. The Common Stock is listed on the NASDAQ National Market under the symbol "BBII".

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

| Fiscal Year Ended December 31, 2000 | Common Stock Price | |
|-------------------------------------|--------------------|----------|
| | High | Low |
| First Quarter | \$ 16.968 | \$ 2.250 |
| Second Quarter | \$ 7.500 | \$ 3.375 |
| Third Quarter | \$ 7.125 | \$ 2.625 |
| Fourth Quarter | \$ 4.625 | \$ 1.500 |
| Fiscal Year Ended December 31, 1999 | High | Low |
| First Quarter | \$ 4.000 | \$ 2.625 |
| Second Quarter | \$ 5.375 | \$ 2.625 |
| Third Quarter | \$ 4.625 | \$ 3.250 |
| Fourth Quarter | \$ 4.625 | \$ 2.375 |

As of March 12, 2001, there were 20,000,000 shares of Common Stock authorized of which 6,454,841 shares were issued and outstanding, held of record by approximately 3,992 stockholders. See also Note 12 of Notes to Consolidated Financial Statements included in Part 2, Item 8 hereunder.

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

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

The statement of income data for each of the fiscal years in the five-year period ended December 31, 2000, and the balance sheet data as of December 31, 2000, 1999, 1998, 1997, and 1996, have been derived from the consolidated financial statements of the Company. This data should be read in conjunction with Item 8--Consolidated Financial Statements and Supplementary Data, and Item 7--Management's Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere herein.

Year Ended Dec

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| | 2000 | 1999 | 1998 |
|---|------------|-----------|----------|
| Consolidated Statement of Income Data: | | | |
| REVENUE: | | | |
| Products | \$ 12,387 | \$ 14,057 | \$ 13,07 |
| Services | 7,083 | 5,741 | 6,19 |
| Total revenue | 19,470 | 19,798 | 19,26 |
| COSTS AND EXPENSES: | | | |
| Cost of products | 7,270 | 7,267 | 7,18 |
| Cost of services | 5,581 | 4,568 | 4,28 |
| Research and development | 2,444 | 3,132 | 2,29 |
| Acquired research and development (3) | -- | -- | 4,23 |
| Selling and marketing | 2,660 | 2,831 | 2,88 |
| General and administrative | 4,919 | 3,451 | 3,33 |
| Impairment of intangible asset (4) | 1,464 | -- | -- |
| Total operating costs and expenses | 24,338 | 21,249 | 24,21 |
| (Loss) income from continuing operations | (4,868) | (1,451) | (4,94) |
| Interest (expense) income, net (5) | (1,594) | (413) | (4 |
| (Loss) income from continuing operations before income taxes .. | (6,462) | (1,864) | (4,99 |
| (Provision for) benefit from income taxes (6) | (1,152) | 744 | 61 |
| Loss from continuing operations before cumulative effect of change in accounting principle | (7,614) | (1,120) | (4,38 |
| Cumulative effect of change in accounting principle (5) | (190) | -- | -- |
| (Loss) income from continuing operations | (7,804) | (1,120) | (4,38 |
| (Loss) income from discontinued operations | (197) | 306 | (|
| Net (loss) income | \$ (8,001) | \$ (814) | \$ (4,38 |
| (Loss) income per share from continuing operations, basic | \$ (1.43) | \$ (0.24) | \$ (0.9 |
| (Loss) income per share from continuing operations, diluted ... | (1.43) | (0.24) | (0.9 |
| Net (loss) income per share, basic | (1.46) | (0.17) | (0.9 |
| Net (loss) income per share, diluted | \$ (1.46) | \$ (0.17) | \$ (0.9 |
| Number of shares used to calculate net (loss) income per share | | | |
| Basic | 5,465 | 4,670 | 4,65 |
| Diluted | 5,465 | 4,670 | 4,65 |
| | | | Decemb |
| | 2000 | 1999 | 199 |
| Consolidated Balance Sheet Data: | | | |
| Working capital | \$ 3,596 | \$ 8,615 | \$ 8,23 |
| Net assets from discontinued operations..... | 1,238 | 1,978 | 1,34 |
| Total assets | 22,549 | 24,934 | 23,03 |
| Long term debt, less current maturities | 5,287 | 7,146 | 3,97 |
| Total stockholders' equity | 7,750 | 13,646 | 14,06 |
| Dividends | -- | -- | -- |

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

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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 four operating segments: "Diagnostics," "Biotech," "Laboratory Instrumentation" and "Other." Two of these, "Diagnostics" and "Laboratory Instrumentation" primarily manufacture products. Within Diagnostics there are three groups: Quality Control Panels, Accurun(R) Run Controls, and Diagnostic Components. The remaining two segments generate primarily service revenue and consist of "BBI Biotech", and "Other" (development stage 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 of Notes to Financial statements for a further discussion of the activities of these segments and Note 13 of Notes to Financial Statements relative to the Company's discontinued clinical laboratory operations.

Effective January 2000, all of the Company's technology related to its drug discovery and vaccine programs, consisting primarily of patents and related sponsored research agreements, were transferred to Panacos Pharmaceuticals, Inc., a wholly-owned subsidiary that the Company formed in October 1999. In November 2000, Panacos sold a majority of its equity to third party investors, reducing the Company's ownership to 30.5% which is held in non-voting preferred securities. As a result, the Company no longer consolidates the results of Panacos. As of November 14, 2000 the Company's investment in Panacos was zero and the Company is no longer required to fund Panacos's operations. Therefore no further losses of Panacos will be recorded by the Company. The Company believes that this will position Panacos to progress to more advanced stages of drug development including clinical trials, while at the same time allowing management to focus more time on the Company's core business.

In December 2000, the Company decided to exit the clinical laboratory segment of the business and accordingly, in February 2001, the Company sold a majority of the assets and the accounts payable of BBI Clinical Laboratories, a wholly-owned subsidiary, to a third party. In connection with the sale, BBI Clinical Laboratories will continue to provide clinical laboratory testing services for at least 180 days from the closing date of the transaction, but in no event later than December 31, 2001. Results of operations for this segment of

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the business are discussed hereunder in the caption entitled "Discontinued Operations." Prior period data has been reclassified to conform to the current format of presentation relative to continuing operations.

PRODUCTS

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

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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 "Other" segment's R&D operation does not currently have any product or service revenue, and no significant revenues are expected in the near future. 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. In this regard, Panacos Pharmaceuticals obtained independent third party equity financing in November 2000, thus terminating the Company's responsibility going forward to fund future research and development activities of Panacos. The Company retains a 30.5% interest in non-voting preferred shares of Panacos.

QUARTERLY FLUCTUATIONS

Historically, the Company's results of operations have been subject to quarterly fluctuations due to a variety of factors, primarily customer purchasing patterns, driven by end-of-year expenditures. In particular, in the Diagnostics segment, the Company's sales of its off-the-shelf Quality Control Products and Diagnostic Components typically have been highest in the fourth quarter and lowest in the first quarter of each fiscal year, whereas OEM product sales may peak in any quarter of the year, depending on the production cycle of a given project. In the Company's 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

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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 (which evolved into Panacos Pharmaceuticals, Inc. in 2000) the Company has expended significant amounts for ongoing research and development spending on new technologies in the Other operating segment.

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, 2000, 1999, and 1998 were \$4.2 million, \$4.0 million, and \$4.1 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:

| | Year Ended December 31, | | |
|--|-------------------------|--------|--------|
| | 2000 | 1999 | 1998 |
| Revenue: | | | |
| Products | 63.6 % | 71.0 % | 67.9 % |
| Services | 36.4 | 29.0 | 32.1 |
| Total revenue | 100.0 | 100.0 | 100.0 |
| Gross profit | 34.0 | 40.2 | 40.5 |
| Operating expenses: | | | |
| Research and development | 12.6 | 15.8 | 11.9 |
| Acquired research and development | -- | -- | 22.0 |
| Selling and marketing | 13.7 | 14.3 | 15.0 |
| General and administrative | 25.3 | 17.4 | 17.3 |
| Impairment of intangible asset | 7.5 | -- | -- |
| Total operating expenses | 59.1 | 47.5 | 66.2 |
| Operating loss from continuing operations | (25.0) | (7.3) | (25.7) |
| Interest expense, net | (8.2) | (2.1) | (0.3) |
| Loss before income taxes and cumulative effect of change in accounting principle | (33.2) | (9.4) | (26.0) |
| Provision for (benefit from) income taxes | (5.9) | 3.8 | 3.2 |
| Cumulative effect of change in accounting principle | (1.0) | -- | -- |

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| | | | |
|--|--------|--------|--------|
| (Loss) income from discontinued operations | (1.0) | 1.5 | -- |
| | ----- | ----- | ----- |
| Net loss | (41.1) | (4.1) | (22.8) |
| | ===== | ===== | ===== |
| Product gross profit | 41.3 % | 48.3 % | 45.1 % |
| Services gross profit | 21.2 % | 20.4 % | 30.7 % |

Years Ended December 31, 2000 and 1999

Revenue

Total revenue from continuing operations decreased 1.7%, or \$328,000, to \$19,470,000 in 2000 from \$19,798,000 in 1999. The decrease in revenue was the result of a decrease in product revenue of 11.9% or \$1,670,000 to \$12,387,000 in 2000 from \$14,057,000 in 1999, partially offset by an increase in service revenue of 23.4% or \$1,341,000 to \$7,083,000 in 2000 from \$5,742,000 in 1999.

Product Revenue

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

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Service Revenue

The increase in service revenue was primarily attributable to increases of \$104,000 from the Diagnostics segment, \$850,000 from the Biotech segment and \$198,000 in the Other segment. The growth in Diagnostics was related to increased service work for in vitro Diagnostic manufacturers including plasma inactivations. The Biotech segment's growth was due to new government contracts for both its repository and research services. The 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 and certain other drug discovery activities associated with Panacos Pharmaceuticals ("Panacos").

Gross Profit

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

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Product Gross Margin

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

Service Gross Margin

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

Research and Development

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

Selling and Marketing

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

General and Administrative

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

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Impairment of Intangible Asset

As part of an ongoing strategic review process, the Company's Board of Directors met in September 2000 to review the progress of its Laboratory Instrumentation segment, and that segment's prospects for the future to determine if any impairment of the segment's goodwill had occurred. Based on information presented at that meeting and subsequent analyses showing lower revenue expectations, management approved a cost reduction plan including a headcount reduction, salary freeze, and sublease of excess manufacturing space. Using the lower revenue projections associated with this plan, the Laboratory Instrumentation segment's undiscounted future cash flows were projected to be less than the carrying value of that segment's goodwill. In accordance with the

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provisions of both "Accounting Principles Board Opinion No. 17 - Intangible Assets" and "Statement of Financial Accounting Standards No. 121 - Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," this segment's goodwill was written down by approximately \$1,464,000 in the third quarter of fiscal year 2000.

Operating Loss

Consolidated loss from continuing operations increased to \$4,868,000 in 2000 versus a \$1,451,000 loss in 1999. The Diagnostics segment's operating income decreased to \$1,015,000 in 2000 from \$2,436,000 in 1999 as a result of decreased revenue and the beneficial effect on 1999's operating income of capitalizing certain employee salaries associated with the ERP System implementation. The Biotech segment's operating loss decreased to \$398,000 in 2000 from \$482,000 in 1999, due to increased revenue from government contracts. The Laboratory Instrumentation segment had an operating loss of \$2,819,000 for 2000 versus a loss for 1999 of \$1,163,000. The year 2000 loss includes a write-down of approximately 80% of their goodwill as of the previous balance sheet date. Excluding this, the Laboratory Instrumentation segment had an operating loss of \$1,355,000 for 2000 as a result of continued low levels of revenue. At the end of the third quarter of 2000, management approved a cost reduction plan in the Laboratory Instrumentation segment including a headcount reduction, salary freeze, and sublease of excess manufacturing space. The operating loss of the Other segment increased to \$2,325,000 in 2000 from \$2,006,000 in 1999 due to planned research and development and patent related costs. The Company continued to invest heavily in the areas of pressure cycling technology and the drug discovery program, through its subsidiary BBI BioSeq and its investment in Panacos Pharmaceuticals.

The Company's ownership of Panacos was reduced to 30.5% in the fourth quarter of 2000 as a result of Panacos obtaining additional equity financing from new investors. Accordingly, the Company terminated consolidation accounting subsequent to November 14, 2000. The Company had recorded Panacos's operating losses for the period January 1, 2000 to November 14, 2000 in the amount of approximately \$790,000.

Interest Expense/Cumulative change in accounting principle

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

Income Taxes

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

Loss from Continuing Operations

Loss from continuing operations increased to \$7,614,000 for the year ended

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December 31, 2000 from \$1,120,000 for the year ended December 31, 1999, as a result of the items discussed above.

Discontinued Operations

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

Summary

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

Years Ended December 31, 1999 and 1998

Revenue

Total revenue from continuing operations increased 2.8%, or \$533,000, to \$19,798,000 in 1999 from \$19,265,000 in 1998. The increase in revenue was the result of an increase in product revenue of 7.5% or \$981,000 to \$14,057,000 from \$13,075,000, partially offset by a decline in service revenue of 7.2% or \$448,000 to \$5,742,000 from \$6,190,000 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.

Service Revenue

The decrease in service revenue was primarily attributable to 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. This decrease was partially offset by a \$942,000 increase in BBI Biotech, and a \$434,000 increase in the Other segment revenue. 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 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. The Company anticipates that new contracts at the BBI Biotech segment will contribute to revenue growth.

Gross Profit

Overall gross profit increased 2.1%, or \$167,000, to \$7,963,000 in 1999 from \$7,796,000 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 \$727,000 to \$1,174,000 in 1999 from \$1,901,000 in 1998 and service gross margin declined to 20.4% in 1999 from 30.7% 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 services. 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 other remaining Company segments do not generate service revenues that would significantly impact segment results.

Research and Development

Research and development costs, exclusive of acquired in-process research and development, increased 36.4% or \$835,000 to \$3,132,000 in 1999 from \$2,297,000 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

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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 declined 1.8% or \$52,000 to \$2,831,000 in 1999 from \$2,883,000 in 1998 as the Company effectively managed costs in this area.

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General and Administrative

General and administrative costs increased 3.5% or \$117,000 to \$3,451,000 in 1999 from \$3,334,000 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 amounting to \$448,000 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 from continuing operations of \$1,451,000 in 1999 versus \$4,949,000 in 1998. Excluding the \$4,231,000 of acquired in-process research and development charges realized in 1998, the Company's operating loss increased \$732,000 to \$1,451,000 in 1999 from \$719,000 in 1998. The Diagnostics operating segment realized an increase in operating income (excluding \$850,000 of acquired research and development costs in 1998) of approximately \$346,000 or 61.8%, as a result of a 6.4% increase in product sales coupled with a relatively steady product 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. In addition, increased research and development expenses at the BBI Biotech segment were primarily responsible for the increased operating loss of \$661,000 in 1999 versus a loss of \$61,000 in 1998. Management anticipates continued strength from its Diagnostics segment. 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.

Interest Expense

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The Company had interest expense of \$420,000 in 1999 versus \$75,000 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.

Income Taxes

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 believed that its valuation allowance was adequate as the Company had planned to return to profitability within six to twelve months, at which point it would have begun to realize the 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 9 to Consolidated Financial Statements in Item 8 hereunder for further detail.

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Loss from Continuing Operations

Loss from continuing operations decreased to \$1,120,000 for the year ended December 31, 1999 from \$4,382,000 for the year ended December 31, 1998, as a result of the items discussed above.

Discontinued Operations

The Clinical Laboratories Services segment of the business, a discontinued operation, recorded income of \$306,000 in 1999 as compared to a loss of \$6,000 in 1998. This segment's growth was led by a 55.1% increase in molecular testing as part of a 37% increase in segment revenues, which more than offset a slight decline in that segment's service gross margin to 30.3% in 1999 from 32.4% in 1998.

Summary

The Company had a net loss of \$814,000 in 1999 versus \$4,389,000 in 1998 as a result of the operating loss (which includes acquired research and development costs expensed in 1998 in the amount of \$4,231,000), interest expense, and the tax benefit described above.

LIQUIDITY AND FINANCIAL CONDITION

In December 2000, the Company made a decision to exit the clinical laboratory testing services segment and in February 2001, BBI Clinical Laboratories, Inc. ("BBICL"), a wholly-owned subsidiary of the Company, sold certain assets and liabilities to a third party for an aggregate purchase price of \$9,500,000, subject to certain post closing adjustments. The Company has retained certain other assets and liabilities of BBICL subsequent to the closing date, which the Company intends to liquidate throughout the remainder of year 2001 as part of its decision to exit this segment of the business. The Company expects to record an after-tax gain in the first quarter of 2001. Closing costs include an estimate of costs associated with disposing of all remaining assets

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and retiring all existing liabilities including a facility lease. The Company expects to utilize in year 2001 certain prior period net operating loss carryforwards, previously reserved for by the Company in year 2000, to offset the tax effect of this future gain. In accordance with a transition services agreement, the Company is required to operate the business in a normal fashion for a minimum of six months subsequent to the sale but in no event longer than one year from the date of sale; substantially all costs associated with operation of the business subsequent to the closing date will be borne by the purchaser. A portion of the proceeds from this sale were used to redeem all outstanding 3% Senior Subordinated Convertible Debentures and to retire the Company's line of credit, as discussed further hereunder.

In August 2000, the Company issued \$3,250,000 of 3% Senior Subordinated Convertible Debentures due August 25, 2003. Net proceeds to the Company amounted to approximately \$2,871,000 after deduction of original issue discount of \$162,500 and associated closing costs of \$216,500. For accounting purposes, a portion of the cash proceeds, amounting to \$327,000, has been allocated to the relative fair value of warrants issued in conjunction with these debentures. In the first quarter of 2001, certain holders of the Company's outstanding 3% Senior Convertible Debentures (the "Debentures") exercised their rights to convert \$1,210,000 of such Debentures into shares of the Company's common stock, in accordance with the conversion formula. The conversion of a portion of these outstanding Debentures and/or the exercise of outstanding warrants to purchase the Company's common stock will have a dilutive impact on our security holders. The conversion price of the Debentures was the lower of: (i) \$3.36 a share or (ii) 90% of the average of the five (5) lowest volume weighted average sales prices of common stock as reported by Bloomberg, L.P. during the 25 business days immediately preceding the date on which any Debenture holder notified the Company that it will convert all or a part of their Debenture into common stock. The terms of the Debenture entitled the Company to redeem any of the outstanding Debenture(s) at a redemption price equal to the number of shares of common stock into which the Debenture(s) was then convertible times the average closing bid price as reported by Bloomberg L.P. for the five (5) trading days immediately prior to the date that the Debenture(s) is called for redemption, plus accrued and unpaid interest. These conversions resulted in the issuance of 801,325

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additional shares of common stock subsequent to December 31, 2000. In addition, in the first quarter of 2001, the Company redeemed the remaining \$2,040,000 of Debentures at face value plus a \$190,000 premium and accrued interest. Unamortized debt discount, debt issuance costs and warrant-related costs associated with the converted Debentures, approximating \$40,000, will be reclassified as an offset to additional paid-in capital, with the remaining \$377,000 of such costs associated with the redeemed Debentures being included in the loss on extinguishment of the Debentures. The Company will also reverse approximately \$528,000 of expenses, previously recorded in 2000, associated with the Debentures beneficial conversion feature. As a result of the above items, the Company expect to record a net loss of approximately \$39,000, relative to this early extinguishment of debt, in the first quarter of 2001. As a result of both the conversions and redemptions, which occurred in the first quarter of 2001, none of the 3%, Senior Subordinated Convertible Debentures remain outstanding subsequent to February 27, 2001.

The Company's working capital position as of December 31, 2000 was adversely affected by the classification of its \$5,763,000 line-of-credit balance as short-term debt. The Company reclassified the debt because in 2000, it violated a financial covenant limiting the amount of allowable losses. In the first quarter of 2001, utilizing proceeds generated by the sale of certain assets of BBICL as discussed above, the Company paid off in full the \$5,763,000

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outstanding balance (plus accrued interest), thereby terminating this line of credit. There were no payment defaults at any time on this line of credit.

In October 1999, the Company formed a new, wholly-owned subsidiary, Panacos Pharmaceuticals, Inc. ("Panacos"), a Delaware corporation. All of the Company's technology related to its drug discovery and vaccine programs, consisting primarily of patents and related sponsored research agreements, were transferred to Panacos effective January 2000. In accordance with its strategic plans, Panacos obtained additional equity financing from third party investors in November 2000 as the first step in raising the substantial amount of capital required to progress to more advanced stages of drug development including human clinical trials. As a result of the new equity financing, the Company retained a 30.5% interest in non-voting preferred shares of Panacos. Accordingly, subsequent to November 14, 2000, the Company no longer consolidates Panacos' results of operations, nor is the Company required to fund any further research and development activities of Panacos.

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

In February 2000, the Company received notice that Paradigm Group, LLC exercised all of its warrants to purchase the Company's common stock. This exercise was expected to result in proceeds to the Company of approximately \$2,100,000. The holders of the warrants were required to pay the exercise price when the registration of the underlying shares became effective which was in December 2000. In August 2000, the Company received a summons and complaint from Paradigm Group, LLC naming the Company as a defendant. The suit, filed in the Circuit Court of Cook County, Illinois, alleged breach of contract claims and fraud against the Company in connection with the sale by the Company to the Paradigm Group, LLC of the above warrants, the exercise of those warrants by Paradigm Group, LLC and a delay in the registration of those shares with the U.S. Securities and Exchange Commission. In December 2000, Paradigm Group, LLC withdrew this lawsuit. The Company believes it is entitled to the funds due from the exercise of the above warrants, however, it has fully reserved the receivable as of December 31, 2000 pending receipt of payment. Additionally, in

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the fourth quarter, the Company expensed approximately \$265,000 of costs incurred related to these warrants and the registration of the underlying shares. The shares related the exercise of these warrants are outstanding from the date the warrants were exercised through the end of the year and have been included in the calculation of weighted average shares outstanding and earnings per share.

The Company has outstanding warrants, with various strike prices, which are exercisable for a total of 457,730 shares of common stock. This represents approximately 8.1% of the Company's issued and outstanding common stock based on the number of shares issued and outstanding as of December 31, 2000.

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Net cash used in continuing operations for the year ended December 31, 2000 was \$2,796,000 as compared to cash use of \$601,000 for year 1999. This increase in operational use of cash was primarily the result of higher operating losses.

Cash used in investing activities was \$1,025,000 for the year 2000 versus \$2,457,000 for the year 1999. During 2000, the Company's BBI Biotech segment invested \$580,000 to build-out its new repository facility in Frederick, Maryland, and approximately \$800,000 relative to the Company's investment in Panacos Pharmaceuticals as discussed further above. In addition, significant investments were made for laboratory and manufacturing equipment. Expenditures in 1999 included approximately \$1,138,000 of computer hardware and software, of which \$807,000 was invested in new enterprise resource planning systems for the Diagnostics and Laboratory Instrumentation segments of the business; this latter amount includes approximately \$448,000 of general and administrative costs capitalized by the Company relative to the implementation of its ERP system in 1999.

Cash provided by financing activities was \$4,783,000 in 2000 versus \$3,560,000 in 1999. During 2000, the net cash provided by debt consisted of the mortgage of approximately \$2,447,000 and the Debentures and related warrants of approximately \$2,531,000 and \$328,000, respectively, as discussed above, less net repayments on the line-of-credit of \$1,383,000. In addition, cash of approximately \$936,000 was received in year 2000 from the exercise of stock options and warrants, exclusive of the 500,000 warrants associated with the Paradigm Group LLC as discussed herein.

As of March 1, 2001, the Company had existing cash balances approximating \$2,100,000 (excluding \$900,000 of restricted cash relating to final post closing adjustments associated with the sale of certain BBICL assets as discussed herein) and believes this amount coupled with internally generated cash flows will be sufficient to fund operations and anticipated capital expenditures for the next year. The Company continually evaluates financing options, as well as other strategic alternatives, in order to maximize shareholder value.

Recent Accounting Pronouncements

Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities" (SFAS 133), as amended, is effective 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 so it does not believe that adoption of SFAS 133 will have a material effect on its financial statements.

In late 2000 and early 2001, the Financial Accounting Standards Board Emerging Issues Task Force ("EITF") reached consensus on a number of revisions to EITF Issue No. 98-5 "Accounting for Convertible Securities with Beneficial Conversions Features or Contingently Adjustable Conversion Ratios." The Securities and Exchange Commission's ("SEC") Observer to the EITF indicated the SEC's preference that the revision relative to the computation of a beneficial conversion features associated with convertible securities be applied to all securities issued after May 20, 1999. The Company has therefore applied this

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adjusted calculation to the beneficial conversion feature associated with its August 2000 issuance of \$3,250,000 of 3% Senior Subordinated Convertible Debentures and accordingly, the Company has included the effects of the revisions, as indicated by the SEC staff member. Approximately \$190,000 of this revised computation is reflected as the cumulative effect of a change in accounting principle in the accompanying financial statements.

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

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

Forward - Looking Information

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

Factors which might cause actual results to differ materially from those projected in the forward-looking statements contained herein include the following: 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 by the September 2000 downsizing of this segment of the business; 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 acquired as part of its purchase of BioSeq, Inc. to the level of commercial utilization; 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; 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 most recent Registration Statements on Form S-3 (SEC File No.'s 333-94379 and 333-46426).

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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, 2000 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, 2000, that is subject to interest rate risk. Fixed rate financial instruments were not evaluated, as the Company believes the risk exposure is not material.

The Company is exposed to concentrations of credit risk in cash and cash equivalents and trade receivables. Cash and cash equivalents are placed with major financial institutions with high quality credit ratings. Trade receivables credit risk exposure is significant as the Company derives a significant portion of its revenues from a small number of customers however this risk is mitigated by the dispersion across different industries and geographies in which the customers operate; in addition to this, approximately 30% of 2000 consolidated revenue was from all branches of the National Institutes of Health, a U.S. Government agency. The Company is exposed to credit-related risks associated with its trade accounts receivable denominated in U.S. Dollars but receivable from foreign customers.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

| | December 31, | |
|---|--------------|------------|
| | 2000 | 1999 |
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 1,782,100 | \$ 276,000 |
| Accounts receivable, less allowances of \$88,981 in 2000 and \$86,796 in 1999 | 3,881,943 | 4,353,000 |
| Inventories | 6,465,548 | 6,461,000 |
| Prepaid expenses and other current assets | 236,731 | 285,000 |
| Income taxes receivable (2000) and deferred (1999) | 212,762 | 934,000 |
| Total current assets | 12,579,084 | 12,311,000 |
| Property and equipment, net | 7,459,283 | 7,752,000 |
| OTHER ASSETS: | | |
| Goodwill and other intangibles, net | 933,793 | 2,571,000 |
| Deferred income taxes | -- | 220,000 |
| Debt issuance costs | 203,523 | 99,000 |
| Other long-term assets | 135,578 | 99,000 |
| Net assets from discontinued operations (Note 15) | 1,237,535 | 1,978,000 |
| | 2,510,429 | 4,869,000 |

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| | | |
|---|---------------|---------------|
| TOTAL ASSETS | \$ 22,548,796 | \$ 24,933,333 |
| | ===== | ===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | \$ 1,232,697 | \$ 1,787,833 |
| Accrued employee compensation | 836,804 | 833,000 |
| Other accrued expenses | 974,606 | 1,076,000 |
| Current maturities of long term debt | 5,840,172 | |
| Deferred revenue and other current liabilities | 99,074 | |
| Total current liabilities | 8,983,353 | 3,696,833 |
| | ----- | ----- |
| LONG-TERM LIABILITIES: | | |
| Long term debt, less current maturities | 2,420,449 | 7,145,000 |
| 3% Senior Subordinated Convertible Debentures | 2,818,375 | |
| Other liabilities | 577,044 | 445,000 |
| COMMITMENTS AND CONTINGENCIES (Note 11) | | |
| STOCKHOLDERS' EQUITY: | | |
| Common stock, \$.01 par value; 20,000,000 shares authorized, 5,652,516 and 4,773,365 issued and outstanding at December 31, 2000 and 1999, respectively | 56,525 | 47,000 |
| Additional paid-in capital | 18,904,862 | 16,809,000 |
| Accumulated deficit | (11,211,812) | (3,210,000) |
| Total stockholders' equity | 7,749,575 | 13,646,000 |
| | ----- | ----- |
| TOTAL LIABILITIES & STOCKHOLDERS' EQUITY | \$ 22,548,796 | \$ 24,933,333 |
| | ===== | ===== |

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

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME

| | Years Ended December | |
|--------------------------------|----------------------|---------------|
| | 2000 | 1999 |
| | ----- | ----- |
| REVENUE: | | |
| Products | \$ 12,387,416 | \$ 14,056,657 |
| Services | 7,082,538 | 5,741,690 |
| Total revenue | 19,469,954 | 19,798,347 |
| | ----- | ----- |
| COSTS AND EXPENSES: | | |
| Cost of products | 7,269,817 | 7,267,273 |
| Cost of services | 5,581,636 | 4,567,863 |
| Research and development | 2,443,779 | 3,131,590 |

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| | | |
|---|----------------|----------------|
| Acquired research and development | -- | 4,230,812 |
| Selling and marketing | 2,659,935 | 2,831,293 |
| General and administrative | 4,918,899 | 3,450,879 |
| Impairment of intangible asset | 1,464,220 | -- |
| | ----- | ----- |
| Total operating costs and expenses | 24,338,286 | 21,248,898 |
| Operating loss from continuing operations | (4,868,332) | (1,450,551) |
| Interest income | 23,598 | 6,146 |
| Interest expense, including beneficial conversion feature (Note 7) | (1,617,311) | (419,980) |
| | ----- | ----- |
| Loss from continuing operations before income taxes and cumulative effect of change in accounting principle | (6,462,045) | (1,864,385) |
| (Provision for) benefit from income taxes | (1,151,940) | 744,093 |
| | ----- | ----- |
| Loss from continuing operations before cumulative effect of change in accounting principle | (7,613,985) | (1,120,292) |
| Cumulative effect of change in accounting principle (Note 7) | (190,223) | -- |
| | ----- | ----- |
| Loss from continuing operations | \$ (7,804,208) | \$ (1,120,292) |
| Discontinued operations (Note 15) (Loss) income from discontinued operations of Clinical Laboratory segment (less income taxes of \$0, \$245,121 and \$49,506 in 2000, 1999 and 1998, respectively | (196,751) | 306,180 |
| | ----- | ----- |
| Net loss | \$ (8,000,959) | \$ (814,112) |
| | ===== | ===== |
| Loss from continuing operations per share, basic & diluted | \$ (1.43) | \$ (0.24) |
| (Loss) income per share from discontinued operations, basic & diluted | \$ (0.03) | \$ 0.07 |
| Net loss per share, basic & diluted | \$ (1.46) | \$ (0.17) |
| Number of shares used to calculate net (loss) income per share basic & diluted | 5,465,358 | 4,669,717 |

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, 2000, 1999 AND 1998

| | Common Stock | | Additional Paid-In Capital | Receiv for Exer Warra |
|--|--------------|--------------------|----------------------------------|-----------------------------|
| | Shares | \$.01 Par Value | | |
| | ----- | ----- | ----- | ----- |
| BALANCE, DECEMBER 31, 1997 | 4,622,566 | \$ 46,226 | \$ 16,029,049 | |
| Stock options and warrants issued with | | | | |

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| | | | | |
|--|-----------|-----------|---------------|----------|
| acquisition | | | 236,327 | |
| Stock options exercised | 45,250 | 453 | 88,696 | |
| Tax benefit of stock options exercised | | | 64,644 | |
| Net loss | | | | |
| | ----- | ----- | ----- | ----- |
| BALANCE, DECEMBER 31, 1998 | 4,667,816 | 46,679 | 16,418,716 | |
| Common stock issued | 53,300 | 533 | 147,905 | |
| Stock warrants issued, net of issuance costs | | | 206,011 | |
| Stock options and warrants exercised | 52,249 | 522 | 36,610 | |
| Net loss | | | | |
| | ----- | ----- | ----- | ----- |
| BALANCE, DECEMBER 31, 1999 | 4,773,365 | 47,734 | 16,809,242 | |
| Common stock issued in connection with Employee Stock Purchase Plan | 8,458 | 84 | 26,264 | |
| Stock warrants issued | | | 1,000 | |
| Stock options and other warrants exercised . | 370,693 | 3,707 | 906,304 | |
| Exercise of Paradigm warrants | 500,000 | 5,000 | 1,954,979 | \$ (2,22 |
| Reserve for exercise of Paradigm warrants .. | | | (1,959,979) | 2,22 |
| Stock warrants issued and beneficial conversion feature in connection with 3% Senior Subordinated Convertible Debentures | | | 1,167,052 | |
| Net loss | | | | |
| | ----- | ----- | ----- | ----- |
| BALANCE, DECEMBER 31, 2000 | 5,652,516 | \$ 56,525 | \$ 18,904,862 | \$ |
| | ===== | ===== | ===== | ===== |

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

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

| | Years Ended December | |
|---|----------------------|--------------|
| | 2000 | 1999 |
| | ----- | ----- |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$ (8,000,959) | \$ (814,112) |
| Income (loss) from discontinued operations | (196,751) | 306,180 |
| | ----- | ----- |
| Loss from continuing operations | (7,804,208) | (1,120,292) |
| Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities: | | |
| Depreciation and amortization | 1,609,454 | 1,338,789 |
| Non-cash interest expense on convertible debentures | 707,704 | -- |
| Cumulative effect of change in accounting principle | 190,223 | -- |
| Impairment of intangible assets | 1,464,220 | -- |
| Provision for doubtful accounts | 2,064 | -- |
| Other liabilities | 190,078 | (320,243) |
| Deferred income tax valuation allowance | 1,155,325 | (447,420) |
| Tax benefit of stock options exercised | -- | -- |
| Acquired research and development | -- | -- |
| Loss on disposal of property and equipment | 4,721 | 35,672 |

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| | | |
|---|--------------|-------------|
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 469,943 | 237,548 |
| Inventories | (3,855) | (73,672) |
| Prepaid expenses and other current assets | 48,316 | 141,608 |
| Receivable for income taxes | (212,762) | |
| Other long-term assets | 11,910 | (2,224) |
| Accounts payable | (554,880) | 29,150 |
| Accrued compensation | 3,571 | (124,042) |
| Other accrued expenses | (101,408) | 395,260 |
| Deferred revenue | 23,897 | (690,760) |
| | ----- | ----- |
| Net cash used in operating activities | (2,795,687) | (600,626) |
| | ----- | ----- |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Acquired research and development | -- | -- |
| Payments for additions to property and equipment | (1,025,460) | (2,456,521) |
| Purchase of intangible assets | -- | -- |
| Acquisitions, net of cash aquired | -- | -- |
| | ----- | ----- |
| Net cash used in investing activities | (1,025,460) | (2,456,521) |
| | ----- | ----- |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from mortgage, net | 2,446,573 | -- |
| Proceeds from issuance of convertible debentures, net | 2,531,023 | -- |
| Proceeds from issuance of warrants | 327,643 | 206,011 |
| Proceeds from issuance of common stock | 936,359 | 185,570 |
| (Repayments) Borrowings on line of credit | (1,383,016) | 3,168,300 |
| Repayments of long-term debt | (75,462) | -- |
| | ----- | ----- |
| Net cash provided by financing activities | 4,783,120 | 3,559,881 |
| | ----- | ----- |
| (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS: | 961,973 | 502,734 |
| Change in cash and cash equivalents provided by | | |
| discontinued operations | 543,959 | (326,480) |
| Cash and cash equivalents, beginning of year | 276,168 | 99,914 |
| | ----- | ----- |
| Cash and cash equivalents, end of year | \$ 1,782,100 | \$ 276,168 |
| | ===== | ===== |
| SUPPLEMENTAL INFORMATION: | | |
| Income taxes paid | \$ 85,119 | \$ 33,391 |
| Interest paid | 416,557 | 414,297 |
| Long-term investment included in acquisition | -- | -- |
| NON-CASH ACTIVITIES: | | |
| Capital lease obligations incurred | \$ 95,577 | \$ -- |

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

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

(1) Business and Significant Accounting Policies

Boston Biomedica, Inc. ("BBI") and Subsidiaries (together, the "Company") provide infectious disease diagnostic products, laboratory instrumentation,

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contract research and specialty infectious disease testing services to the in vitro diagnostic industry, government agencies, blood banks, hospitals and other health care providers worldwide as of December 31, 2000. The Company also invests in new technologies related to infectious diseases. The Company is subject to risks common to companies in the biotechnology, medical device and diagnostic industries, including but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with governmental regulations.

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

(i) Principles of Consolidation

The consolidated financial statements include the accounts of BBI and its wholly-owned subsidiaries, BBI Biotech Research Laboratories, Inc. ("BBI Biotech"), BBI Source Scientific, Inc. ("BBI Source"), and BBI BioSeq, Inc. ("BBI BioSeq"). BBI consists primarily of the Diagnostic Products segment as well as the executive corporate office. In January 2000, the Company incorporated Panacos Pharmaceuticals, Inc., ("Panacos"). All of the Company's technology related to its drug discovery and vaccine programs, consisting of primarily patents and related sponsored agreements, were transferred to Panacos effective January 2000. Panacos was accounted for as a consolidated subsidiary of the Company during the period January 1, 2000 to November 14, 2000, subsequent to which Panacos obtained independent third party funding and the Company ceased consolidation of Panacos as a wholly-owned subsidiary. As of November 14, 2000 the Company's investment in Panacos was zero and the Company is no longer required to fund Panacos's operations. Therefore no further losses of Panacos will be recorded by the Company. The Company retains a 30.5% interest in non-voting preferred shares of Panacos. All significant intercompany accounts and transactions have been eliminated in the consolidation.

Subsequent to December 31, 2000, the Company sold certain assets of BBI Clinical Laboratories, Inc. ("BBICL") to a third party in conjunction with its decision to exit the clinical laboratory business segment. Accordingly, the accompanying financial statements have been reclassified to present BBICL's net assets and results of operations as discontinued operations.

(ii) Use of Estimates

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

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(1) Business and Significant Accounting Policies (Continued)

(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 \$562,000, \$1,998,000, and \$1,388,000 for the years ended December 31, 2000, 1999, and 1998, respectively.

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

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

Total revenue related to long-term contracts was approximately \$5,082,000, \$4,457,000, and \$4,175,000 for the years ended December 31, 2000, 1999 and 1998, respectively. Total contract costs associated with these agreements were approximately \$5,540,000, \$4,323,000, and \$3,950,000 for the years ended December 2000, 1999 and 1998, 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.

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 fiscal year ended December 31, 2000. The adoption of this standard by the Company did not have a material impact on the accompanying financial statements.

(iv) Cash and cash equivalents

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

(v) Research and Development Costs

Research and development costs are expensed as incurred.

(vi) Inventories

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

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(1) Business and Significant Accounting Policies (Continued)

(vii) Property and Equipment

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

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 became 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 businesses 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. Upon the occurrence of a material circumstance, such as the failure of certain technology to demonstrate promise that it may gain commercial acceptance or the failure of a business segment to achieve certain performance objectives, management reassesses the value of associated assets and if appropriate at that time, will recognize an impairment charge. (See Note 5.)

(x) Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred taxes arise from temporary differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance is provided for net deferred tax assets if, based on the

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weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Tax credits are recognized when realized using the flow through method of accounting. In the year ended December 31, 2000, the Company' established a full valuation allowance for all of its deferred tax assets based on applicable accounting standards and in consideration of incurring three consecutive years of losses (see Note 10).

(xi) Concentration of Credit Risk

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

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(1) Business and Significant Accounting Policies (Continued)

(xii) Deferred Revenue

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

(xiii) Computation of Earnings (Loss) per Share

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

Potentially dilutive securities having a net effect of 2,500, 68,023 and 192,826 common shares were not included in the computation of diluted loss per share because to do so would have been antidilutive for the years ended December 31, 2000, 1999 and 1998, respectively.

(xiv) Segment Reporting

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

(xv) Recent Accounting Standards

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Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities" (SFAS 133), as amended, is effective 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 so it does not believe that adoption of SFAS 133 will have a material effect on its financial statements.

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

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

(xvi) Reclassifications

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

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(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 of the Company's 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

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\$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:

| Item | Estimated Useful Life | Fair Value | Allocated Purchase Price |
|--|-----------------------|---------------|--------------------------|
| Acquired in-process research and development | -- | \$ 8,764,000 | \$ 3,381,000 |
| Patents | 16 years | 2,017,000 | 778,000 |
| Other assets | 3 - 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 may spend up to \$3.0 million in years 2001 through 2003 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.

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 1998, 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.

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

Year Ended
December 31, 1998
Pro Forma

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| | |
|-----------------------------|---------------|
| Revenues | \$ 26,081,077 |
| Operating income (loss) ... | (1,474,694) |
| Net income (loss) | (989,327) |
| EPS | \$ (0.21) |

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, 2000 and 1999 consisted of the following:

| | 2000 | 1999 |
|-----------------------|-------------|-------------|
| | ----- | ----- |
| Raw materials | \$3,029,962 | \$2,219,512 |
| Work-in-process | 1,753,867 | 1,845,778 |
| Finished goods | 1,681,719 | 2,396,403 |
| | ----- | ----- |
| | \$6,465,548 | \$6,461,693 |
| | ===== | ===== |

(4) Property and Equipment

Property and equipment at December 31, 2000 and 1999 consisted of the following:

| | 2000 | 1999 |
|---|--------------|--------------|
| | ----- | ----- |
| Laboratory and manufacturing equipment | \$ 3,228,054 | \$ 3,006,313 |
| Management information systems | 3,315,397 | 3,119,064 |
| Office equipment | 882,584 | 838,950 |
| Automobiles | 135,485 | 135,485 |
| Leasehold improvements | 2,696,561 | 2,114,261 |
| Land, building and improvements | 2,672,240 | 2,611,733 |
| | ----- | ----- |
| | 12,930,321 | 11,825,806 |
| Less accumulated depreciation | 5,471,038 | 4,073,087 |
| | ----- | ----- |
| Net book value | \$ 7,459,283 | \$ 7,752,719 |
| | ===== | ===== |

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Depreciation expense for the years ended December 31, 2000, 1999 and 1998 was approximately \$1,410,000, \$1,126,000, and \$886,000 respectively. Included in 2000, 1999 and 1998 land, building and improvements is approximately \$0, \$203,000 and \$1,345,000, respectively, of construction in progress.

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(4) Property and Equipment (continued)

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 \$90,000 and \$7,000 for the years ended December 31, 2000 and 1999, respectively.

(5) Intangible Assets

Intangible assets at December 31, 2000 and 1999 consisted of the following:

| | 2000 | 1999 |
|-------------------------------------|------------|-------------|
| | ----- | ----- |
| Goodwill | \$ 820,248 | \$2,284,468 |
| Patents | 795,880 | 795,880 |
| Licenses | 6,359 | 6,359 |
| | ----- | ----- |
| | 1,622,487 | 3,086,707 |
| Less accumulated amortization | 688,694 | 515,303 |
| | ----- | ----- |
| Net book value | \$ 933,793 | \$2,571,404 |
| | ===== | ===== |

Amortization expense for the years ended December 31, 2000, 1999 and 1998 was approximately \$173,000, \$213,000, and \$177,000 respectively.

As part of an ongoing strategic review process, the Company's Board of Directors met in late September 2000 to review the progress of its Laboratory Instrumentation segment, and that segment's prospects for the future. Based on new updated information presented at this meeting and subsequent analyses showing lower revenue expectations, management approved implementation of a cost reduction plan including a headcount reduction, salary freeze, and sublease of excess manufacturing space. Using the assumptions associated with this revised business plan, the Company estimated future net undiscounted cash inflows and cash outflows over the remaining original amortization period of that segment's goodwill, and concluded an impairment had occurred. These annual net future cash inflows and outflows were then discounted at a rate commensurate with the business risks inherent with the future operations of the Laboratory Instrumentation segment, and thus, in accordance with the provisions of both "Accounting Principles Board Opinion No. 17 - Intangible Assets" and "Statement of Financial Accounting Standards No. 121 - Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," this segment's

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goodwill was written down by approximately \$1,464,000 in year 2000. The remaining net balance of goodwill associated with the Laboratory Instrument segment is approximately \$249,000 as of December 31, 2000.

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

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

The Company had four operating segments as of December 31, 2000, as a result of its decision in late 2000 to exit the clinical laboratory segment of the business. The Diagnostics segment serves the worldwide in vitro diagnostics industry, including users and regulators of their test kits, with quality control products, and test kit components. The Biotech segment pursues third party contracts to help fund the development of products and services for the other segments, primarily with agencies of the United States Government. The Laboratory Instrumentation segment sells diagnostic instruments primarily to the

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

worldwide in vitro diagnostic industry on an OEM basis, and also performs in-house instrument servicing. "Other" consists of research and development primarily in pressure cycling technology ("PCT"). The Company performs research in the development of PCT, with particular focus in the areas of nucleic acid purification and pathogen inactivation. The "Other" segment's R&D operations does not currently have any significant product or service revenue, and no significant revenue is expected in the near future. This 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's underlying accounting records are maintained on a legal entity basis for government and public reporting requirements, as well as for segment performance and internal management reporting. Inter-segment sales are recorded on a "third party best price" basis and are significant in measuring segment operating results. Throughout 1999, the cost of most corporate functions are included in the Diagnostic Products segment as the senior management group has dual responsibility to this segment as well as the Company. Pursuant to the August 1999 reorganization, many of the senior managers and a few other employees were segregated from the Diagnostics segment to form a Corporate operating unit, effective January 2000. The following segment information has been prepared in accordance with the internal accounting policies of the Company, as described above. Prior year data has been restated, where feasible, to conform to the current year presentation format.

Operating segment revenue for the years ended December 31, 2000, 1999 and 1998 were as follows:

| | 2000 | 1999 | 1998 |
|-------------------|-----------|-----------|-----------|
| | ----- | ----- | ----- |
| Diagnostics | \$ 10,863 | \$ 11,837 | \$ 11,277 |

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| | | | |
|----------------------------------|-----------|-----------|-----------|
| Biotech | 7,428 | 6,297 | 5,355 |
| Laboratory Instrumentation | 2,309 | 2,923 | 3,929 |
| Other | 532 | 434 | -- |
| Eliminations | (1,662) | (1,693) | (1,296) |
| | ----- | ----- | ----- |
| Total revenue | \$ 19,470 | \$ 19,798 | \$ 19,265 |
| | ===== | ===== | ===== |

Operating segment (loss) income for the years ended December 31, 2000, 1999 and 1998 were as follows:

| | | | |
|-------------------------------------|------------|------------|------------|
| | 2000 | 1999 | 1998 |
| | ----- | ----- | ----- |
| Diagnostics | \$ 1,015 | \$ 2,436 | \$ 1,962 |
| Biotech | (398) | (482) | (214) |
| Laboratory Instrumentation | (2,819) | (1,163) | (1,187) |
| Other | (2,325) | (2,006) | (1,085) |
| Eliminations | (341) | (236) | (194) |
| Acquired research & development ... | -- | -- | (4,231) |
| | ----- | ----- | ----- |
| Total loss from operations | \$ (4,868) | \$ (1,451) | \$ (4,949) |
| | ===== | ===== | ===== |

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

Operating segment depreciation and amortization expense for the years ended December 31, 2000, 1999 and 1998 were as follows:

| | | | |
|---|----------|----------|----------|
| | 2000 | 1999 | 1998 |
| | ----- | ----- | ----- |
| Diagnostics | \$ 665 | \$ 537 | \$ 408 |
| Biotech | 582 | 419 | 346 |
| Laboratory Instrumentation (1) | 1,717 | 299 | 292 |
| Other | 83 | 84 | 17 |
| | ----- | ----- | ----- |
| Total depreciation and amortization..... | \$ 3,047 | \$ 1,339 | \$ 1,063 |
| | ===== | ===== | ===== |

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

Identifiable operating segment assets are all located in the United States, and as of December 31, 2000 and 1999 were as follows:

| | |
|-------|-------|
| 2000 | 1999 |
| ----- | ----- |

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| | | |
|----------------------------------|-----------|-----------|
| Diagnostics | \$ 11,183 | \$ 13,375 |
| Biotech | 4,693 | 4,643 |
| Laboratory Instrumentation | 2,141 | 3,789 |
| Other | 3,294 | 1,148 |
| | ----- | ----- |
| Total assets | \$ 21,311 | \$ 22,955 |
| | ===== | ===== |

Operating segment capital expenditures for the years ended December 31, 2000, 1999 and 1998 were as follows:

| | 2000 | 1999 | 1998 |
|----------------------------------|----------|----------|----------|
| | ----- | ----- | ----- |
| Diagnostics | \$ 283 | \$ 1,315 | \$ 1,472 |
| Biotech | 818 | 944 | 1,234 |
| Laboratory Instrumentation | 19 | 164 | 96 |
| Other | 1 | 34 | -- |
| | ----- | ----- | ----- |
| Total capital expenditures | \$ 1,121 | \$ 2,457 | \$ 2,802 |
| | ===== | ===== | ===== |

Revenue by geographic area for the years ended December 31, 2000, 1999 and 1998 are as follows:

| | 2000 | 1999 | 1998 |
|------------------------|-----------|-----------|-----------|
| | ----- | ----- | ----- |
| United States | \$ 15,295 | \$ 15,758 | \$ 15,162 |
| Europe | 2,594 | 2,509 | 2,453 |
| Pacific Rim | 841 | 818 | 1,063 |
| Total all others | 740 | 713 | 587 |
| | ----- | ----- | ----- |
| Total | \$ 19,470 | \$ 19,798 | \$ 19,265 |
| | ===== | ===== | ===== |

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

Revenue of Product and Service classes in excess of 10% of consolidated revenue from continuing operations (excludes inter-segment sales) for the years ended December 31, 2000, 1999 and 1998 were as follows:

| | 2000 | 1999 | 1998 |
|-------------------------------------|----------|----------|----------|
| | ----- | ----- | ----- |
| Quality Control Products | \$ 8,210 | \$ 9,445 | \$ 9,369 |
| Government Contracts | 5,929 | 4,530 | 3,535 |
| Laboratory Instrument Products | 1,953 | 2,578 | 2,291 |

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The government contract revenues are from United States government agencies, primarily various branches of the National Institutes of Health (NIH) and represent the only customer with revenue in excess of 10% of consolidated revenue in each of the years ended December 31, 2000, 1999 and 1998.

(7) Debt

Effective June 30, 1999, the Company entered into an amended revolving line of credit agreement (the "Amended Line") with its bank, increasing the facility to \$10 million from \$7.5 million. The Amended Line bears interest at the Company's option based on either the base rate plus 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 Amended Line contains covenants regarding the Company's total liabilities to tangible net worth ratio, minimum debt service coverage ratio, and maximum net loss. The Amended Line further provides for restrictions on the payment of dividends, incurring additional debt, and the amount of capital expenditures.

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

On August 25, 2000, the Company entered into Securities Purchase Agreements providing for the issuance of \$3,250,000 (face value) 3% Senior Subordinated Convertible Debentures due August 25, 2003, (the "Debentures"). Proceeds to the Company, net of a 5% original issue discount and debt issuance costs, amounted to \$2,858,000, of which \$327,000 has been allocated to the relative fair value of the associated common stock purchase warrants. The fair value of the warrants was determined using the Black Scholes option-pricing model and the following assumptions: a risk free interest rate of 6.02%, a volatility factor of 91.17%, a contractual life of 5 years and no expected dividend yield. The Company then allocated the proceeds of the Debentures, net of the original issue discount (\$3,087,500), on a pro-rata basis using the calculated fair value of the warrants (\$318,000) and the fair value of the Debentures (\$2,685,000). This resulted in proceeds of approximately \$327,000 and \$2,761,000 being allocated to the relative fair value of the warrants and the Debentures, respectively. The Debentures are convertible into the Company's common stock commencing November 24, 2000, at a conversion price equal to the lesser of (i) \$3.36 per share or (ii) 90% of the average of the five lowest volume weighted average sales prices of Common Stock as reported by Bloomberg L.P. during the twenty-five business days immediately preceding the date on which the Debenture holders notify the Company of their intention to convert all or part of the Debenture into Common Stock. In connection with this transaction, the Company issued warrants to

(7) Debt (continued)

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purchase up to 135,556 shares of the Company's common stock at an exercise price of \$3.60 per share. Interest on the Debentures is payable quarterly in arrears commencing September 30, 2000. The Debentures are subordinate to both the Company's line of credit (which was terminated in February 2001) and mortgage on its West Bridgewater, MA facility. The Company may elect at any time to redeem all or any portion of the remaining unpaid principal amount of the Debentures for cash. In addition, upon receipt of a notice of conversion from a holder of the Debentures, the Company may elect to redeem that portion being converted for cash in lieu of common stock of the Company. In both cases, the redemption price equals the number of shares of common stock into which the Debenture being redeemed is convertible, times the average closing bid price of the Company's common stock for the five preceding trading days.

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

Original issue discount and associated debt issuance costs of \$162,500 and \$230,000, respectively, are being amortized ratably over the three-year life of the underlying debt as additional interest expense. Also, in accordance with Emerging Issues Task Force Issues 98-5 and 00-27, proceeds of \$840,000 have been allocated to the beneficial conversion feature of the Debentures by decreasing the value of the debt and increasing additional paid in capital. Of this, \$351,000 was originally calculated in the third quarter when the Debentures were issued. The additional amount of \$489,000 was calculated in the fourth quarter using the accounting conversion method preferred by the SEC pursuant to EITF 00-27 which clarified the method of calculating the beneficial conversion feature. The amount allocated to the beneficial conversion feature was valued using conversion method (ii) from above as of the date of the transaction as it was determined to be the most beneficial to the holders of the Debentures. This amount was expensed over the initial 90-day non-convertible period. The remaining difference between the relative fair value of the Debentures and the face value of the Debentures (as a result of the \$327,000 of proceeds allocated to the warrants) will be expensed as interest expense over the three-year term of the Debentures. For the year ended December 31, 2000, the Company recorded a charge of \$898,000 (including \$190,223 for the cumulative effect of a change in accounting principle noted above) due to amortization of the beneficial conversion feature, warrant costs and original issue discount/debt issuance costs associated with the Company's August 2000 issuance of \$3,250,000 3% Senior Subordinated Convertible Debentures. Under the Debenture agreements the Company is subject to certain financial covenants by which a default in its line of credit financial covenants will cause a default on the Debentures. The Company has received a waiver from the holders of the debentures regarding the covenant violation.

In the first quarter of 2001, certain holders of the Company's outstanding 3% Senior Convertible Debentures (the "Debentures") exercised their rights to convert \$1,210,000 of such Debentures into shares of the Company's common stock, in accordance with the conversion formula. These conversions resulted in the issuance of 801,325 additional shares of common stock subsequent to December 31, 2000. In addition, the Company redeemed the remaining \$2,040,000 of Debentures at face plus a \$190,000 premium and accrued interest. Unamortized debt discount, debt issuance costs and warrant-related costs associated with the converted Debentures, approximating \$231,000 will be debited to additional paid-in capital, with the remaining \$377,000 of such costs associated with the redeemed Debentures being included in the loss on extinguishment of the Debentures. In addition, the Company will reverse approximately \$528,000 of expense previously recorded in 2000 associated with the Debentures beneficial conversion feature.

Accordingly, the Company will record a net loss of approximately \$39,000

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relative to this early extinguishment of debt in the first quarter of 2001. As a result of both the conversions and redemptions, which occurred in the first quarter of 2001, none of the 3%, Senior Subordinated Convertible Debentures remain outstanding subsequent to February 27, 2001.

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(7) Debt (continued)

On April 5, 2000, the Company borrowed \$2,447,000, net of related costs, under a mortgage agreement on its West Bridgewater, MA facility, of which approximately \$2,466,000 remains outstanding as of December 31, 2000. The Company used the funds to reduce the outstanding balance of its existing line of credit. The principal amount of the note issued in connection with the mortgage is due on March 31, 2010. During the first five years the note carries an interest rate of 9.75%; after five years the rate charged will be .75% greater than the Corporate Base Rate then in effect. The mortgage precludes the payment of dividends on the Company's common stock and contains certain other restrictive covenants. Under this mortgage agreement the Company is subject to certain financial covenants by which a default in its line of credit financial covenants will cause a default on this note. The Company has received a waiver from this lending institution regarding the covenant violation. Monthly payments on this mortgage are based on a 20 year amortization schedule with a balloon payment representing the remaining balance due in full on March 10, 2010. The mortgage is collateralized by the Company's West Bridgewater, MA facility. Principal payments due on the Company's mortgage agreement are approximately \$49,000, \$54,000, \$60,000, \$66,000 and \$72,000 for each of the years ended December 31, 2001, 2002, 2003, 2004 and 2005, respectively.

(8) Other Liabilities

Included in long-term liabilities at December 31, 2000 and 1999 are the present value of future minimum royalty payments of approximately \$55,000 and \$139,000 payable to the former owners of BioSeq, Inc. (see Note 2).

(9) Income Taxes

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

| | 2000 | 1999 | 1998 |
|--|-------------|--------------|--------------|
| | ----- | ----- | ----- |
| Current (benefit) provision: federal | \$ -- | \$ (226,368) | \$ (63,868) |
| Current provision: state | -- | 2,168 | 2,168 |
| | ----- | ----- | ----- |
| Total current (benefit) provision | -- | (224,200) | (61,700) |
| Deferred (benefit) provision: federal | 879,557 | (373,497) | (437,315) |
| Deferred (benefit) provision: state | 272,383 | (146,396) | (114,890) |
| | ----- | ----- | ----- |
| Total deferred (benefit) provision | 1,151,940 | (519,893) | (552,205) |
| | ----- | ----- | ----- |
| Total (benefit) provision for income taxes ... | \$1,151,940 | \$ (744,093) | \$ (613,905) |
| | ===== | ===== | ===== |

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

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| | 2000 | 1999 |
|---|-------------|--------------|
| | ----- | ----- |
| Current deferred taxes: | | |
| Inventory | \$ 562,134 | \$ 174,338 |
| Accounts receivable allowance | 355,611 | 298,271 |
| Technology licensed | 277,250 | 299,883 |
| Other accruals | 173,504 | 162,298 |
| Less: valuation allowance | (1,368,499) | -- |
| | ----- | ----- |
| Total current deferred tax assets | -- | 934,790 |
| Long term deferred taxes: | | |
| Accelerated tax depreciation | (232,282) | (335,880) |
| Goodwill and intangibles | 594,657 | 19,961 |
| Tax credits | 252,589 | 252,589 |
| Operating loss carryforwards | 3,094,247 | 1,082,665 |
| Less: valuation allowance | (3,709,211) | (798,800) |
| | ----- | ----- |
| Total long term deferred tax assets (liabilities), net..... | -- | 220,535 |
| | ----- | ----- |
| Total net deferred tax assets | \$ -- | \$ 1,155,325 |
| | ===== | ===== |

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(9) Income Taxes (continued)

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

The Company had net operating loss carryforwards for federal income tax purposes of approximately \$7,550,000 and \$2,300,000 at December 31, 2000 and 1999, respectively. These net operating loss carryforwards expire at various dates from 2011 through 2020. Included in this number are loss carryforwards of approximately \$2,000,000 that were obtained through the acquisition of BioSeq, Inc. These carryforwards expire from 2011 through 2018. The Company has established a valuation allowance of \$798,800 to reserve for this entire loss since the acquisition of BioSeq, Inc.

The Company had net operating loss carryforwards for state income tax purposes of approximately \$9,200,000 and \$5,000,000 at December 31, 2000 and 1999, respectively. These net operating loss carryforwards expire at various dates from 2001 through 2020. Included in this number are loss carryforwards of approximately \$2,000,000 that were obtained through the acquisition of BioSeq, Inc. These carryforwards expire from 2001 through 2003. As discussed above, the Company has established a valuation allowance to reserve for this entire loss since the acquisition of BioSeq, Inc.

Included in the net operating loss carryforwards discussed above is a deferred tax asset of approximately \$1,200,000 reflecting the benefit of deductions from the exercise of stock options. The benefit from this deferred tax asset will be recorded as a credit to additional paid-in-capital when realized.

As of December 31, 2000, the Company had approximately \$47,000 of alternative minimum tax credits, which do not expire, and \$205,000 of federal research credits, which expire from 2011 to 2018.

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

| | 2000 | 1999 | 1998 |
|---|-------|-------|-------|
| | ----- | ----- | ----- |
| Federal tax (benefit) provision rate | (34%) | (34%) | (34%) |
| State tax (benefit) provision, net of federal benefit | (6%) | (6%) | (1%) |
| Nondeductable writeoff of acquired research and development ... | | | 23% |
| Non-cash deductions and other permanent items | 4% | | |
| Effect of subsidiary leaving the group | (6%) | | |
| Valuation allowance | 59% | 2% | 1% |
| | ----- | ----- | ----- |
| Effective income tax (benefit) provision rate | 17% | (38%) | (11%) |
| | ===== | ===== | ===== |

The Company's federal income tax return for fiscal year 1997 is currently under examination by the Internal Revenue Service. The Company's Massachusetts state income tax returns for the years 1996-1998 have been reviewed and closed pursuant to a recently completed examination. Any assessments or potential assessments are not expected to have a material adverse effect on the accompanying financial statements.

(10) Commitments and Contingencies

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

In May 2000, the Company acquired laboratory equipment pursuant to a three-year capital lease at 12% financing, resulting in total payments of approximately \$115,000 over the life of the lease agreement.

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(10) Commitments and Contingencies (continued)

At December 31, 2000, future minimum lease payments under non-cancelable leases, excluding discontinued operations, is as follows:

| Year Ended | Operating Leases | Capital Leases |
|---|------------------|----------------|
| ----- | ----- | ----- |
| 2001 | \$ 1,128,000 | \$ 38,000 |
| 2002 | 858,000 | 38,000 |
| 2003 | 870,000 | 16,000 |
| 2004 | 889,000 | - |
| 2005 | 915,000 | - |
| 2006 and thereafter | 1,186,000 | - |
| | ----- | ----- |
| Total minimum lease payments | \$ 5,846,000 | 92,000 |
| | ===== | |
| Less amount representing interest | | (15,000) |
| | | ----- |
| Present value of minimum lease payments | | \$ 77,000 |
| | | ===== |

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The Company has entered into a non-cancelable sublease agreement with a third party that will offset the future minimum lease payments by \$184,000. Rent expense, net of sublease income consisted of the following:

| | 2000 ----- | 1999 ----- | 1998 ----- |
|-------------------------|---------------|---------------|---------------|
| Basic expense | \$ 1,109,000 | \$ 1,094,000 | \$ 797,000 |
| Sublease income | (42,000) | -- | -- |
| | ----- | ----- | ----- |
| Rent expense, net | \$ 1,067,000 | \$ 1,094,000 | \$ 797,000 |
| | ===== | ===== | ===== |

In addition, as discussed further in Note 13 hereunder, the Company is subject to future minimum lease payments in connection with the discontinued operations of its Clinical Laboratory segment of \$161,000, \$161,000, \$161,000, \$161,000, and \$67,000 in 2001, 2002, 2003, 2004 and 2005, respectively. The Company has entered into a Transition Services agreement with the purchaser whereby the purchaser has subleased these premises for the remainder of 2001. The Company has accrued a portion of the remaining lease commitment in 2001 as part of the calculation of the gain on the sale of certain assets from the Clinical Laboratory segment.

The Company's California and Maryland facility's leases include scheduled base rent increases over the term of the lease. The amount of base rent payments is charged to expense using the straight-line method over the term of the lease. As of December 31, 2000 and 1999, the Company has recorded a long-term liability of \$262,000 and \$306,000, respectively (\$337,000 and \$341,000 including the current portion) to reflect the excess of rent expense over cash payments since inception of the lease. In addition to base rent, the Company pays a monthly allocation of the operating expenses and real estate taxes for the California and Maryland facilities.

In April 1999, the Company increased its 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 was committed to pay approximately \$44,000 per quarter for three years. These costs, charged to research and development expense, provide for the rights to any new anti-HIV compounds and derivatives developed in the course of this sponsored research, provided certain regulatory approvals are obtained from the FDA. Effective November 2000, all rights, costs and obligations under this agreement were transferred to Panacos Pharmaceuticals, Inc., of which the Company has a 30.5% ownership of non-voting securities as of December 31, 2000.

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(11) Retirement Plan

In January 1993, the Company adopted a retirement savings plan for its employees, which has been qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the plan through payroll deductions within statutory limitations and subject to any limitations included in the plan. Company contributions are made at the discretion of management. To date, no such contributions have been made. During 2000, 1999 and 1998 the Company recognized administrative expense of approximately \$30,000, \$30,000, and \$32,000, respectively in connection with the plan.

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(12) Stockholders' Equity

Common Stock

In July 1999, the Company's Board of Directors approved the 1999 Employee Stock Purchase Plan. The Company adopted this plan, which allows eligible employees to purchase shares of the Company's stock at 85% of market value as determined at the beginning and the end of the offering period. A total of 250,000 shares have been reserved for this plan. As of December 31, 2000, 8,458 shares had been 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-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, 2000, 1,999,500 shares were reserved for incentive stock options, of which 1,031,185 are available for future grants. At December 31, 2000, 1,098,680 shares were reserved under the nonqualified stock option plan of which 251,270 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 an exercise price of \$4.25 and 100,000 common stock purchase warrants with an exercise price of \$5.25. Paradigm Group paid the Company \$50,000 for the warrants. In addition, National Securities received 40,000 common stock purchase warrants with an exercise price of \$4.25, 10,000 common stock purchase warrants with an exercise price of \$5.25, and 25,000 common stock purchase warrants with an exercise price of \$8.00, as transaction fee.

In February 2000, the Company received notice that Paradigm Group, LLC exercised all of their warrants to purchase the Company's common stock. The holders of the warrants were required to pay the exercise price when the registration of the underlying shares became effective which was in December 2000. In August 2000, the Company received a summons and complaint from Paradigm Group, LLC naming the Company as a defendant. The suit, filed in the Circuit Court of Cook County, Illinois, alleged breach of contract claims and fraud against the Company in connection with the sale by the Company to the Paradigm Group, LLC of the above warrants, the exercise of those warrants by Paradigm Group, LLC and a delay in the registration of those shares with the U. S. Securities and Exchange Commission. In December 2000, Paradigm Group, LLC withdrew this lawsuit. While the Company believes that it is entitled to the funds due from the exercise of the above warrants, it has fully reserved the receivable due to concerns over its collectability. Additionally, in the fourth quarter, the Company has expensed approximately \$265,000 of expenses related to these warrants and the registration of the underlying shares. The 500,000 shares associated with the exercise of these warrants are included in the total shares outstanding as well as in the calculation of earnings (loss) per share from the date the warrants were exercised through the end of the year.

(12) Stockholders' Equity (continued)

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 2000, 1999, and 1998.

| | 2000 ----- | 1999 ----- | 1998 ----- |
|-------------------------------------|---------------|---------------|---------------|
| Risk-free interest rate | 5.77% | 5.26% | 4.69% |
| Volatility factor | 98.54% | 76.68% | 75.57% |
| Weighted average expected life | 5.1 years | 5.1 years | 5.0 years |
| Expected dividend yield | -- | -- | -- |

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

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

| 2000 ----- | 1999 ----- | 1998 ----- |
|---------------|---------------|---------------|
|---------------|---------------|---------------|

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| | | | |
|--|----------------|----------------|-------------|
| Net loss - as reported | \$ (8,000,959) | \$ (814,112) | \$ (4,388,7 |
| Net loss - pro forma | \$ (9,161,689) | \$ (1,394,564) | \$ (4,776,8 |
| Net loss per share - as reported, basic\$ ^a | \$ (1.46) | \$ (0.17) | \$ (0. |
| Net loss per share - pro forma, basic a | \$ (1.68) | \$ (0.30) | \$ (1. |

The average fair value of options granted during 2000, 1999 and 1998 is estimated as \$2.67, \$2.63 and \$1.77, respectively.

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(12) Stockholders' Equity (continued)

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

| | Stock Options | | Warrants | |
|--|---------------|----------------------------------|---------------|----------------------------------|
| | Shares | Weighted Average price per share | Shares | Weighted Average price per share |
| Balance outstanding, December 31, 1997 | 1,026,093 | 4.28 | 160,000 | 11.48 |
| Granted | 358,836 | 3.80 * | 100,000 | 2.50 |
| Exercised | (45,250) | 1.97 | -- | -- |
| Cancelled | (165,013) | 6.05 | -- | -- |
| Balance outstanding, December 31, 1998 | 1,174,666 | 2.75 ** | 260,000 | 8.34 |
| Granted | 260,500 | 3.91 | 579,153 | 4.73 |
| Exercised | (47,249) | 0.52 | (5,000) | 2.50 |
| Cancelled | (107,688) | 3.56 | -- | -- |
| Balance outstanding, December 31, 1999 | 1,280,229 | 3.00 | 834,153 | 5.80 |
| Granted | 489,600 | 3.05 | 145,556 | 3.64 |
| Exercised | (353,254) | 2.51 | (521,979) *** | 4.38 |
| Cancelled | (171,397) | 3.51 | -- | -- |
| Balance outstanding, December 31, 2000 | 1,245,178 | 3.06 | 457,730 | 6.81 |

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

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

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

The following table summarizes information concerning options outstanding and exercisable as of December 31, 2000:

| Options Outstanding | Opti |
|---------------------|------|
|---------------------|------|

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| Range of Exercise Price | Weighted Average Remaining Life | Number of Options | Weighted Average Exercise Price | Number of Options |
|-------------------------|---------------------------------|-------------------|---------------------------------|-------------------|
| 0.00 - 1.50 | 0.3 | 42,000 | 1.50 | 42,000 |
| 1.51 - 2.00 | 0.8 | 27,000 | 1.65 | 27,000 |
| 2.01 - 2.50 | 7.0 | 469,100 | 2.50 | 153,100 |
| 2.51 - 3.00 | 1.5 | 42,986 | 2.83 | 33,505 |
| 3.01 - 3.50 | 6.2 | 445,942 | 3.26 | 300,669 |
| 3.51 - 4.00 | 8.8 | 60,150 | 4.00 | 3,000 |
| 4.01 - 4.50 | 8.7 | 130,500 | 4.32 | 29,312 |
| 4.51 - 5.00 | 8.6 | 25,000 | 4.68 | 12,500 |
| 5.51 - 7.00 | 5.2 | 2,500 | 7.00 | 2,500 |
| 0.00 - 7.00 | 6.5 | 1,245,178 | 3.06 | 603,586 |

Preferred Stock

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

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(13) Subsequent Events

In December 2000, the Company made a decision to exit the clinical laboratory testing services segment and in February 2001, BBI Clinical Laboratories, Inc., a wholly-owned subsidiary of the Company, sold certain assets and liabilities of its clinical laboratory business to a third party for an aggregate purchase price of \$9,500,000, of which \$900,000 is being held in escrow subject to certain post closing adjustments. The Company has retained certain other assets and liabilities of BBICL, primarily property plant and equipment together with a facility lease subsequent to the closing date, which the Company intends to liquidate throughout the remainder of year 2001 as part of its decision to exit this segment of the business. In accordance with a transition services agreement, the Company is required to operate the business in a normal fashion for a minimum of six months subsequent to the sale but in no event longer than one year from the date of sale; substantially all costs associated with operating the business subsequent to the closing date will be borne by the purchaser.

The Company expects to record an after-tax gain in the first quarter of 2001, subject to post closing adjustments. Closing costs include estimate to dispose of all remaining assets and retire all existing liabilities including the facility lease. The Company expects to utilize in year 2001 certain prior period net operating loss carryforwards, previously reserved for by the Company in year 2000, to offset the tax effect of this future gain. All financial data presented in the accompanying financial statements has been reclassified to reflect discontinued operations of this segment of the business for all periods presented. Revenues from discontinued operations net of intercompany eliminations of \$197,287, \$368,979 and \$367,617 were \$8,366,995, \$9,472,741 and \$6,816,317 in 2000, 1999 and 1998 respectively.

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

| 2000 | 1st Qtr | 2nd Qtr | 3rd Qtr | 4th Qtr |
|------|---------|---------|---------|---------|
|------|---------|---------|---------|---------|

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| | | | | |
|---|-----------|-----------|------------|------------|
| | ----- | ----- | ----- | ----- |
| Total revenue | \$ 4,539 | \$ 5,535 | \$ 4,534 | \$ 4,862 |
| Gross profit | 1,631 | 2,160 | 1,537 | 1,291 |
| Net loss from continuing operations before cumulative effect of change in accounting principle | (608) | (276) | (4,695) | (2,035) |
| Loss from continuing operations | (608) | (276) | (4,695) | (2,225) |
| Loss from discontinued operations | (63) | (16) | (71) | (47) |
| | ----- | ----- | ----- | ----- |
| Net (loss) | \$ (671) | \$ (292) | \$ (4,766) | \$ (2,272) |
| | ===== | ===== | ===== | ===== |
| (Loss) per share from continuing operations before cumulative effect of change in accounting principle, basic & diluted | \$ -- | \$ -- | \$ -- | \$ (0.36) |
| (Loss) per share from continuing operations, basic & diluted | (0.12) | (0.05) | (0.84) | (0.39) |
| (Loss) per share from discontinued operations, basic & diluted | (0.01) | -- | (0.01) | (0.01) |
| | ----- | ----- | ----- | ----- |
| Net (loss) per share, basic & diluted | \$ (0.13) | \$ (0.05) | \$ (0.85) | \$ (0.40) |
| | ===== | ===== | ===== | ===== |
| 1999 | 1st Qtr | 2nd Qtr | 3rd Qtr | 4th Qtr |
| | ----- | ----- | ----- | ----- |
| Total revenue | \$ 4,725 | \$ 4,783 | \$ 4,925 | \$ 5,365 |
| Gross profit | 1,921 | 2,001 | 2,036 | 2,005 |
| Loss from continuing operations | (309) | (281) | (337) | (193) |
| Loss from discontinued operations | 72 | 56 | 80 | 98 |
| | ----- | ----- | ----- | ----- |
| Net (loss) | \$ (237) | \$ (225) | \$ (257) | \$ (95) |
| | ===== | ===== | ===== | ===== |
| (Loss) per share from continuing operations, basic & diluted | \$ (0.07) | \$ (0.06) | \$ (0.07) | \$ (0.04) |
| (Loss) per share from discontinued operations, basic & diluted | 0.02 | 0.01 | 0.02 | 0.02 |
| | ----- | ----- | ----- | ----- |
| Net (loss) per share, basic & diluted | \$ (0.05) | \$ (0.05) | \$ (0.05) | \$ (0.02) |
| | ===== | ===== | ===== | ===== |

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 in item 14 of this Form 10-K, present fairly, in all material respects, the financial position of Boston Biomedica, Inc. and its subsidiaries at December 31, 2000 and 1999, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2000 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the 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

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

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 27, 2001

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

None.

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PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Certain 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 16 of this report.

The following table sets forth certain information with respect to the Directors of the Company.

| Name | Age | Position | Director Since |
|---------------------------|-----|----------|----------------|
| ---- | --- | ----- | ----- |
| Francis E. Capitanio (1) | 57 | Director | 1986 |
| Calvin A. Saravis (1) (2) | 71 | Director | 1978 |

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| | | | |
|---------------------------|----|---|------|
| William R. Prather | 54 | Senior Vice President, Finance and Business Development, Treasurer and Director | 1999 |
| Kevin W. Quinlan (1) | 51 | President and Chief Operating Officer, and Director | 1978 |
| Richard T. Schumacher (2) | 50 | Chief Executive Officer and Chairman of the Board | 1978 |

(1) Member of the Company's Audit Committee

(2) Member of the Company's Compensation Committee

Mr. Capitanio has served as a Director of the Company since January 1986. Since 1997, Mr. Capitanio has served as President of Kalisto Biologicals, Inc. From 1996 to 1997, he served as an independent consultant in the medical diagnostics industry. From 1980 to 1996, he served as President, Treasurer and Director of Diatech Diagnostics Inc. (formerly Immunotech Corporation), an in vitro diagnostics company and a wholly owned subsidiary of Healthcare Technologies Ltd. Mr. Capitanio received an M.B.A. from the Sloan School of Management, Massachusetts Institute of Technology and a B.S. in metallurgy from Massachusetts Institute of Technology.

Dr. Saravis has served as a Director of the Company since 1978. Since 1984, he has been an Associate Professor of Surgery (Biochemistry) at Harvard Medical School and an Associate Research Professor of Pathology at Boston University School of Medicine. From 1971 to 1997, Dr. Saravis was a Senior Research Associate at the Mallory Institute of Pathology and from 1979 to 1997, he was a Senior Research Associate at the Cancer Research Institute--New England Deaconess Hospital. Dr. Saravis received his Ph.D. in immunology and serology from Rutgers University.

Dr. Prather, a Director of the Company since 1999, has been Senior Vice President, Finance and Business Development since August 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 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 his 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.

Mr. Quinlan, a Director of the Company since 1978, has served as President and Chief Operating Officer since August 1999. From January 1993 to August 1999, he served as Senior Vice President, Finance, Treasurer, and Chief Financial Officer. From 1990 to December 1992, he was the Chief Financial Officer of ParcTec, Inc., a New York-based leasing company. Mr. Quinlan served as Vice President and Assistant Treasurer of American Finance Group, Inc. from 1981 to 1989 and was employed by Coopers & Lybrand (now PricewaterhouseCoopers L.L.P.) 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.

Mr. Schumacher, the Founder of the Company, has been the Chief Executive Officer and Chairman of the Board since 1992 and served as President from 1986 to August 1999. Mr. Schumacher served as the Director of Infectious Disease Services for Clinical Sciences Laboratory, a New England-based medical reference laboratory, from 1986 to 1988. From 1972 to 1985, Mr. Schumacher was employed by the Center for Blood Research, a nonprofit medical research institute associated

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with Harvard Medical School. Mr. Schumacher received a B.S. in zoology from the University of New Hampshire.

Section 16(a) Beneficial Ownership Reporting Compliance

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

Based solely on the Company's review of the copies of such Form(s) it has received and written representations from certain reporting persons, the Company believes that all of its Executive Officers, Directors and greater than 10% stockholders complied with all Section 16(a) filing requirements applicable to them during the Company's fiscal year ended December 31, 2000.

ITEM 11. EXECUTIVE COMPENSATION

The following Summary Compensation Table sets forth the compensation of each of the Chief Executive Officer and the four other most highly compensated executive officers of the Company who were serving as Executive Officers at the end of fiscal 2000 and whose total annual salary and bonus, if any, exceeded \$100,000 for services in all capacities to the Company during the fiscal year ended December 31, 2000 (the "Named Executive Officers").

| Summary Compensation Table | | | | | | Long Compe Secur Unde Stock |
|---|----------------------|---------------------|---------------|-------------|--------------------------------------|---|
| Name and Principal Position | Fiscal Year Ended | Annual Compensation | | | Other Annual Compensation (\$) | |
| | | Salary (\$) | Bonus (\$) | (\$) | | |
| Richard T. Schumacher Chief Executive Officer and Chairman of the Board | 12/31/00 | \$229,279 | -- | \$1,550 (1) | | |
| | 12/31/99 | 229,010 | -- | 1,520 (1) | 25 | |
| | 12/31/98 | 200,002 | \$5,000 | 370 (1) | 15 | |
| Kevin W. Quinlan President and Chief Operating Officer, and Director | 12/31/00 | \$178,596 | -- | \$3,575 (1) | | |
| | 12/31/99 | 168,075 | -- | -- | 17 | |
| | 12/31/98 | 143,347 | \$4,000 | -- | 10 | |
| Richard C. Tilton Senior Vice President, Science and Technology | 12/31/00 | \$131,095 | -- | \$6,000 (3) | 12 | |
| | 12/31/99 | 135,203 | -- | 6,000 (3) | | |
| | 12/31/98 | 127,019 | \$3,000 | 6,000 (3) | 6 | |
| Mark M. Manak, Senior Vice President and General Manager | 12/31/00 | \$137,846 | -- | -- | 5 | |
| | 12/31/99 | 129,894 | -- | -- | | |
| | 12/31/98 | 118,510 | \$3,000 | -- | 6 | |
| Patricia E. Garrett Senior Vice President and General Manager | 12/31/00 | \$126,465 | -- | -- | 12 | |
| | 12/31/99 | 124,873 | -- | -- | 10 | |
| | 12/31/98 | 112,402 | -- | -- | 17 | |

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- (1) Consists of personal usage of Company vehicle
- (2) Includes the value of premiums paid for a term life insurance policy
- (3) Consists of automobile allowance
- (4) Includes the value of imputed income from group life insurance

The following tables set forth certain information with respect to the stock options granted to and exercised by the Named Executive Officers during fiscal 2000 and the aggregate number of and value of options exercisable and un-exercisable held by the Named Executive Officers during fiscal 2000.

Options Granted in Fiscal Year 2000

| Individual Grants | | | | |
|--------------------------|---|--|-------------------------|-----------------|
| Name | Number of Securities Underlying Options Granted (#) | Total Options Granted to Employees in 2000 | Exercise Price (\$/Sh.) | Expiration Date |
| Richard T. Schumacher | -- | -- | -- | -- |
| Kevin W. Quinlan | -- | -- | -- | -- |
| Richard C. Tilton, Ph.D. | 12,000 | 2.45% | 2.50 | 12/01/10 |
| Mark M. Manak, Ph.D. | 5,000 | 1.02% | 4.00 | 02/03/10 |
| Patricia E. Garrett | 12,000 | 2.45% | 2.50 | 12/01/10 |

(1) The 5% and 10% assumed rates of annual compounded stock price appreciation are mandated by the rules of the Securities and Exchange Commission and do not represent the Company's estimate or projection of future Common Stock prices.

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

| Name | Shares Acquired on Exercise (#) | Value Realized (\$) | Number of Securities Underlying Unexercised Options at Year End (#) (2) | |
|--------------------------|---------------------------------|---------------------|---|----------------|
| | | | Exercisable | Un-exercisable |
| Richard T. Schumacher | 90,000 | 288,500 | 26,785 | 20,595 |
| Kevin W. Quinlan, | -- | -- | 69,375 | 18,125 |
| Richard C. Tilton, Ph.D. | 35,000 | 274,050 | 20,500 | -- |
| Mark M. Manak, Ph.D. | -- | -- | 40,500 | 8,000 |
| Patricia E. Garrett | 10,000 | 67,500 | 20,500 | 22,500 |

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- (1) The "value realized" represents the excess of the fair market value over the purchase price at the time of purchase based upon the closing price of the Common Stock on the Nasdaq National Market on the date of exercise, minus the respective option exercise price.
- (2) Includes the number of shares underlying both "exercisable" (i.e. vested) and "un-exercisable" (i.e. unvested) stock options as of December 31, 2000.
- (3) The values of "in-the-money" options reflect the positive spread between the exercise price of any such existing stock options and the closing year-end per share price of the Common Stock of \$1.625.

Compensation of Directors

Non-employee Directors of the Company received cash compensation of \$6,000 for their services in year 2000. Commencing in year 2001, non-employee Directors will receive a quarterly stipend of \$1,500, for a yearly total of \$6,000 each. In addition, in year 2001, each non-employee director who is a member of the Audit Committee will receive an additional \$500 per quarter for a yearly total of \$2,000 each. Each Director is eligible to receive options to purchase Common Stock under the Company's 1999 Non-Qualified Stock Option Plan.

Compensation Committee Interlocks and Insider Participation

The Board of Directors makes decisions regarding executive compensation 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 options to purchase Common Stock. Mr. Schumacher serves as the Chief Executive Officer and Chairman of the Board of the Company. Dr. Saravis is neither a former nor current officer nor employee of the Company.

Compensation Committee Report

The Compensation Committee of the Board of Directors is comprised of Mr. Schumacher and one non-employee Director, Dr. Saravis. The functions of the Compensation Committee include making recommendations and presentations to the Board of Directors on compensation levels, including salaries, incentive plans, benefits and overall compensation for officers and Directors and issuance of stock options to officers, Directors and employees. Subsequent to the recommendation of the Compensation Committee, the Board of Directors then votes on these proposals.

The objectives of the Compensation Committee in determining the type and amount of Executive Officer compensation are to provide a level of base compensation which allows the Company to attract and retain superior talent. The Compensation Committee endeavors to align the Executive Officer's interests with the success of the Company through participation in the Company's Employee Stock Option Plan, which provides the Executive Officer with the opportunity to build a substantial ownership interest in the Company.

The compensation of Executive Officers includes cash compensation, the grant of stock options, and participation in benefit plans generally available to employees. In determining base salary, the Compensation Committee considers executive compensation for comparably sized companies as well as the individual experience and performance of each Executive Officer. The Compensation Committee then recommends to the Board of Directors base salaries at a level that it believes is comparable to cash compensation of officers with similar responsibilities in similarly situated corporations. The Board makes final determination of recommendations.

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Each of the Executive Officers, including Mr. Schumacher, and all full-time employees are eligible to receive grants of options under the Company's employee stock option plans. The employee stock option plans are used to provide incentives to officers and employees and to associate more closely the interests of such persons with stockholders' interests and the long-term success of the Company. In determining the number of options to be granted to each Executive Officer or employee, the Compensation Committee makes a subjective determination based on factors such as the individual's level of responsibility, performance, and number of options held. The Board of Directors then acts on the recommendation of the Compensation Committee. During fiscal 2000, a total of 29,000 options were granted to the Named Executive Officers noted above under the employee stock option plans.

During the fiscal year ended December 31, 2000, Mr. Schumacher, the Company's Chief Executive Officer, received a base salary of \$229,279. The Compensation Committee, and the Board of Directors, believes that this compensation is comparable to the cash compensation of Chief Executive Officers of comparable companies. Mr. Schumacher was not granted any options to purchase shares of Common Stock in 2000.

Compensation Committee

Richard T. Schumacher

Calvin A. Saravis

Performance Graph

The following graph compares the change in the Company's cumulative total stockholder return from October 31, 1996, when the Company's Common Stock became publicly traded, to March 31, 2001 including December 31, 2000, which includes the last trading day of fiscal 2000, with the cumulative total return on the Nasdaq Stock Market Index (Composite) and the Nasdaq Biotechnology Stocks Index (SIC 2830-2839 U.S. and Foreign) for that period.

EDGAR REPRESENTATION OF DATA POINTS USED IN PRINTED GRAPHIC

LEGEND

| Index Description | 10/31/96 | 12/31/96 | 12/31/97 | 12/31/98 | 12/31/99 | 12/31/00 | 3/31/01 |
|-------------------------------------|----------|----------|----------|----------|----------|----------|---------|
| Boston Biomedica, Inc. | 100.0 | 87.1 | 70.97 | 38.31 | 37.10 | 20.97 | 21.7 |
| Nasdaq Stock Market (Biotechnology) | 100.0 | 102.11 | 102.04 | 147.23 | 296.87 | 365.12 | 258.0 |
| Nasdaq Stock Market (Composite) | 100.0 | 105.69 | 128.56 | 179.51 | 333.14 | 202.25 | 150.6 |

Assumes \$100 invested on October 31, 1996 in the Company's Common Stock, the Nasdaq Stock Market Index (Biotechnology) and the Nasdaq Stock Market Index (Composite), and the reinvestment of any and all dividends.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information as of March 31, 2001 concerning beneficial ownership of Common Stock by each Director, each nominee for Director, each named Executive Officer in the Summary Compensation Table under "Executive Compensation" below, all Executive Officers and Directors as a group, and each person known by the Company to be the beneficial owner of 5% or more of the Company's Common Stock. This information is based upon information

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received from or on behalf of the named individuals.

| Name * | Number of Shares of Common Stock Beneficially Owned | Percent of Clas |
|--|---|-----------------|
| Richard T. Schumacher (1) (2) * c/o Boston Biomedica, Inc. 375 West Street West Bridgewater, MA 02379 | 866,657 | 13.35% |
| Kevin W. Quinlan (1) | 97,475 | 1.49% |
| William R. Prather (1) (4) | 82,018 | 1.26% |
| Mark M. Manak (1) (3) | 69,311 | 1.07% |
| Patricia E. Garrett | 50,000 | ** |
| Richard C. Tilton (1) | 38,000 | ** |
| Calvin A. Saravis (1) | 13,456 | ** |
| Francis E. Capitanio (1) | 2,500 | ** |
| All Executive Officers and Directors as a group (11 Persons) (1) (2) (3) (4) | 1,251,495 | 19.26% |
| Paradigm Group, L.L.C. * 3000 Dundee Road, Suite 105 Northbrook, IL 60062 | 425,000*** | 6.58% |
| Richard P. Kiphart (5) * c/o William Blair & Company, L.L.C. 222 West Adams Street Chicago, IL 60606 | 879,685 | 13.61% |

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

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

*** These shares are not entitled to vote until they are fully paid for.

(1) Includes the following shares subject to options exercisable within 60 days after March 31, 2001: Mr. Schumacher - 31,130; Mr. Quinlan - 71,875; Dr. Prather - 52,918, Dr. Tilton - 20,500; Dr. Manak - 43,250;

Dr. Garrett - 25,000; Dr. Saravis - 2,500; and Mr. Capitanio - 2,500

(2) Includes 30,500 shares held of record by Mr. Schumacher's spouse.

Excludes certain additional shares held by other relatives of Mr. Schumacher as to which Mr. Schumacher disclaims beneficial ownership.

(3) Includes 4,000 shares held of record by Mr. Manak's daughter and 20,466 in Mr. Manak's name.

(4) Includes 28,300 shares held by Avon Medical Profit Sharing Plan and Trust. Dr. Prather and his spouse are the sole trustees and beneficiaries of the trust.

(5) Includes 357,791 shares held of record by Shoreline Micro-Cap Fund I LP of which Mr. Kiphart has reported to the Securities and Exchange Commission on February 26, 2001 as having sole voting power.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

In August 1999, the Company sold 500,000 warrants to purchase the Company's stock to Paradigm Group L.L.C., a private investment company. The private placement consisted of 400,000 common stock purchase warrants with an exercise price of \$4.25 and 100,000 common stock purchase warrants with an exercise price of \$5.25. Paradigm Group paid the Company \$50,000 for the warrants. In addition,

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National Securities received 40,000 common stock purchase warrants with an exercise price of \$4.25, 10,000 common stock purchase warrants with an exercise price of \$5.25, and 25,000 common stock purchase warrants with an exercise price of \$8.00, as transaction fee. In February 2000, the Company received notice that Paradigm Group, L.L.C. exercised all of their warrants to purchase the Company's common stock. The holders of the warrants were required to pay the exercise price when the registration of the underlying shares became effective which was in December 2000. See also Part I Item 3 "Legal Proceedings" herein.

In August 2000, the Company issued \$3,250,000 of 3% Senior Subordinated Convertible Debentures to investors, of which \$780,000 were issued to Mr. Richard P. Kiphart and \$220,000 were issued to Shoreline Micro-Cap Fund I L.P. In January 2001, Mr. Kiphart and Shoreline Micro-Cap Fund I L.P. exercised their conversion rights associated with these debentures. Mr. Kiphart has subsequently indicated in a Schedule 13D filing with the Securities and Exchange Commission that he has sole voting power of 897,685 shares of common stock of the Company, which includes 357,791 shares held in the name of Shoreline Micro-Cap Fund I L.P. as of February 6, 2001. See also Part II Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Financial Condition" herein.

PART IV

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

(a) 1. Index to Financial Statements:

| | |
|--|----|
| Consolidated Balance Sheets as of December 31, 2000 and 1999 | 33 |
| Consolidated Statements of Income for the three years ended December 31, 2000 | 34 |
| Consolidated Statements of Changes in Stockholders' Equity for the three years ended December 31, 2000 | 35 |
| Consolidated Statements of Cash Flows for the three years ended December 31, 2000 .. | 36 |
| Notes to Consolidated Financial Statements | 37 |
| Report of Independent Accountants | 55 |

(a) 2. Financial Statement Schedule:

| | |
|---|----|
| Schedule II-Valuation and Qualifying Accounts | 61 |
|---|----|

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

(a) 3. Exhibits:

Exhibit No.

3.1 Amended and Restated Articles of Organization of the Company

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- 3.2 Amended and Restated Bylaws of the Company
- 4.1 Specimen Certificate for Shares of the Company's Common Stock
- 4.2 Description of Capital Stock (contained in the Restated Articles of Organization of the Company filed as Exhibit 3.1)
- 4.3 Form of warrants issued in connection with Paradigm Group
- 4.4 3% Senior Subordinated Convertible Debenture issued to GCA Strategic Investment Fund Limited
- 4.5 Warrant issued to GCA Strategic Investment Fund Limited
- 4.6 Warrant issued to Wharton Capital Partners, Ltd.
- 4.7 Warrant issued to DP Securities, Inc.
- 4.8 Registration Rights Agreement, dated as of August 25, 2000, by and among Boston Biomedica, Inc., Wharton Capital Partners, Ltd., DP Securities, Inc. and GCA Strategic Investment Fund Limited
- 4.9 3% Senior Subordinated Convertible Debenture issued to Richard P. Kiphart
- 4.10 3% Senior Subordinated Convertible Debenture issued to Shoreline Micro-Cap Fund, L.P.
- 4.11 Warrant issued to Richard P. Kiphart
- 4.12 Warrant issued to Shoreline Micro-Cap Fund, L.P.
- 4.13 Registration Rights Agreement dated as of August 25, 2000, by and among Boston Biomedica, Inc., Richard P. Kiphart and Shoreline Micro-Cap Fund, L.P.
- 10.1 Agreement, dated January 17, 1994, between Roche Molecular Systems, Inc. and the Company
- 10.2 Exclusive License Agreement, dated April 28, 1999, between the University of North Carolina at Chapel Hill and the Company
- 10.3 Agreement, dated October 1, 1995, between Ajinomoto Co., Inc. and the Company
- 10.4 Lease Agreement, dated July 28, 1995, for New Britain, Connecticut Facility between MB Associates and the Company
- 10.5 1987 Non-Qualified Stock Option Plan*
- 10.6 Employee Stock Option Plan*
- 10.7 1999 Non-Qualified Stock Option Plan*
- 10.8 1999 Employee Stock Purchase Plan*
- 10.9 Underwriters Warrants, each dated November 4, 1996, between the Company and each of Oscar Gruss & Son Incorporated and Kaufman Bros., L.P.
- 10.11 Contract, dated March 1, 1997, between National Cancer Institute and the Company
- 10.12 Lease Agreement, dated May 16, 1997, for Gaithersburg, Maryland facility between B.F. Saul Real Estate Investment Trust and the Company
- 10.13 Lease Agreement dated January 30, 1995 for Garden Grove, California facility

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between TR Brell, Cal Corp. and Source Scientific, Inc., and Assignment of Lease, dated July 2, 1997, for Garden Grove, California facility between Source Scientific, Inc. and BBI Source Scientific

10.14 Contract, dated July 1, 1998, between the National Institutes of Health and the Company (NO1-A1-85341)

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10.15 Contract, dated July 1, 1998, between the National Heart Lung and Blood Institute and the Company (NO1-HB-87144)

10.16 Line of Credit Agreement with BankBoston dated June 30, 1999

10.17 Agreement with Paradigm Group for the purchase of warrants dated August 18, 1999

10.18 Agreement with MDBio for the purchase of common stock and common stock warrants, dated September 30, 1999

10.19 Lease Agreement dated September 30, 1999, for Frederick, Maryland facility, between MIE Properties, Inc., and the Company.

10.20 Sponsored Research Agreement with the University of North Carolina, Chapel Hill and the Company, dated, April 28, 1999 and the Company.

10.21 Repository Contract with National Institute of Allergy and Infectious Disease, Division of AIDS (NO1-A1-95381), dated August 16, 1999.

10.22 Securities Purchase Agreement dated as of August 25, 2000, by and among Boston Biomedica, Inc., and GCA Strategic Investment Fund Limited

10.23 Securities Purchase Agreement dated as of August 25, 2000, by and among Boston Biomedica, Inc., Richard P. Kiphart and Shoreline Micro-Cap Fund, L.P.

10.24 Mortgage and Security Agreement dated March 31, 2000

10.25 Asset Purchase Agreement dated February 20, 2001, by and between BBI Clinical Laboratories, Inc., Boston Biomedica, Inc. and Specialty Laboratories, Inc.

21.1 Subsidiaries of the registrant

23 Consent of PricewaterhouseCoopers LLP

99 Audited Financial Statements of BioSeq, Inc., for the years ended December 31, 1997, 1996 and for the period October 17, 1994 (Date of Inception) to December 31, 1997.

A Incorporated by reference to the registrant's Registration Statement on Form S-1 (Registration No. 333-10759) (the "Registration Statement"). The number set forth herein is the number of the Exhibit in said Registration Statement.

B Incorporated by reference to Exhibit No. 10.17 of the Registration Statement.

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

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

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- E Form 10-Q for the fiscal quarter ended March 31, 1997.
Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1997.
- F Incorporated by reference to the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.
- G Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1998.
- H Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 1999.
- I Incorporated by reference to the registrant's proxy statement, filed with the Securities and Exchange Commission on June 14, 1999.
- J Incorporated by reference to the registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1999.
- K Incorporated by reference to the registrant's Report on Form 8-K filed September 8, 2000.
- L Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 1999.
- M Incorporated by reference to the registrant's Report on Form 8-K filed March 8, 2001.
- N Incorporated by reference to the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.

- * 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.

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(b) REPORTS ON FORM 8-K.

The Registrant did not file any Current Reports on Form 8-K during the quarter ended December 31, 2000.

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: May 2, 2001

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.

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| SIGNATURES | TITLES |
|---|--|
| /s/ Richard T. Schumacher ----- Richard T. Schumacher | Director and Principal Executive Officer |
| /s/ Kevin W. Quinlan ----- Kevin W. Quinlan | Director and Principal Accounting and Financial Officer |
| ----- Francis E. Capitanio | Director |
| ----- William R. Prather, R.Ph. MD. | Director and Treasurer |
| /s/ Calvin A. Saravis, Ph.D. ----- Calvin A. Saravis, Ph.D. | Director |

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SCHEDULE II

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES
VALUATION AND QUALIFYING ACCOUNTS

| Allowance for Doubtful Accounts | Balance at Beginning of Period | Additions | Recoveries | Deductions |
|------------------------------------|--------------------------------------|------------|------------|-------------|
| | ----- | ----- | ----- | ----- |
| 2000 | \$ 86,796 | \$ 2,064 | \$ 2,185 | \$ (2,064) |
| 1999 | 151,564 | 1,751 | -- | (66,519) |
| 1998 | 103,008 | 87,229 | -- | (38,673) |
| | | | | |
| Inventory Reserve | | | | |
| 2000 | \$ 601,167 | \$ 176,397 | \$ -- | \$ (11,864) |
| 1999 | 533,252 | 145,497 | -- | (77,582) |
| 1998 | 631,565 | 16,932 | -- | (115,245) |

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