# AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON OCTOBER 25, 1996 REGISTRATION NO. 333-10759

SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

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AMENDMENT NO.2 TO FORM S-1 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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BOSTON BIOMEDICA, INC. (EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

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MASSACHUSETTS 2835 04-2652826 (STATE OR OTHER JURISDICTION OF (PRIMARY STANDARD INDUSTRIAL I.R.S. EMPLOYER INCORPORATION OR ORGANIZATION) CLASSIFICATION CODE NUMBER) IDENTIFICATION NUMBER)

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375 WEST STREET, WEST BRIDGEWATER, MASSACHUSETTS 02379 (508) 580-1900 (ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER, INCLUDING AREA CODE, OF REGISTRANT'S PRINCIPAL EXECUTIVE OFFICES)

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RICHARD T. SCHUMACHER,
PRESIDENT AND CHIEF EXECUTIVE OFFICER
BOSTON BIOMEDICA, INC.
375 WEST STREET
WEST BRIDGEWATER, MASSACHUSETTS 02379
(508) 580-1900

(NAME, ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER, INCLUDING AREA CODE, OF AGENT FOR SERVICE)

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BROWN, RUDNICK, FREED & GESMER
ONE FINANCIAL CENTER
BOSTON, MASSACHUSETTS 02111

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TEL: (212) 318-3000 FAX: (212) 752-5958

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APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: As soon as practicable after this Registration Statement is declared effective by the Securities and Exchange Commission.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. [x]

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THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.

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### SUBJECT TO COMPLETION, DATED OCTOBER 25, 1996

PROSPECTUS

1,600,000 SHARES

[LOGO]

BOSTON BIOMEDICA, INC. COMMON STOCK

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All of the 1,600,000 shares of Common Stock (the "Common Stock") offered hereby are being sold by Boston Biomedica, Inc. (the "Company").

Prior to this Offering, there has been no public market for the Common Stock of the Company. It is currently estimated that the initial public offering price will be between \$8.00 and \$10.00 per share. See "Underwriting" for information relating to the determination of the initial public offering price. The Common Stock has been approved for quotation on the Nasdaq National Market under the symbol "BBII."

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SEE "RISK FACTORS" BEGINNING ON PAGE 6 FOR A DISCUSSION OF CERTAIN FACTORS THAT SHOULD BE CONSIDERED BY PROSPECTIVE PURCHASERS OF THE COMMON STOCK OFFERED HEREBY.

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THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE

UN	IDERWRITING	
PRICE TO	DISCOUNTS AND	PROCEEDS TO
PUBLIC	COMMISSIONS(1)	COMPANY(2)

Per Share	\$ \$	\$
Total(3)	\$ \$	\$

Total(3) \$ \$ \$

- (1) Excludes the value of warrants to be issued to the Underwriters and a 1% non-accountable expense allowance payable to the Underwriters, of which \$40,000 has been paid to date. The Company has agreed to indemnify the Underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended. See "Underwriting."
- (2) Before deducting expenses payable by the Company estimated to be \$792,000.

(3) The Company has granted the Underwriters an option, exercisable within 30
days of the date hereof, to purchase up to 240,000 additional shares of
Common Stock at the Price to Public less Underwriting Discounts and
Commissions to cover over-allotments, if any. If all such additional shares
are purchased, the total Price to Public, Underwriting Discounts and
Commissions and Proceeds to Company will be \$ , \$ and \$
respectively. See "Underwriting."

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OSCAR GRUSS & SON INCORPORATED

KAUFMAN BROS., L.P.

THE DATE OF THIS PROSPECTUS IS ,

, 1996.

Information contained herein is subject to completion or amendment. A Registration Statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold nor may offers to buy be accepted prior to the time the Registration Statement becomes effective. This Prospectus shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any State in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such State.

## Description of photograph:

Under the caption "Total Quality System," there is a collage of the Company's products which are a part of its Total Quality System. In the upper left corner is a photograph of a TQS Qualification Panel, proceeding clockwise to the upper right corner is a photograph of an Accurun 1(R) vial and pipette superimposed over a typical Levey-Jennings daily quality control chart. In the lower right corner is a photograph of a lab technician operating equipment in one of the Company's laboratories, and finally, in the lower left corner, is a photograph of Anti-HIV 1 Western Blots for seven different Company Panel Products.

The BBI logo is a trademark of the Company. Accurun 1(R) is a registered trademark of the Company. Accurun(tm) is a trademark of the Company.

IN CONNECTION WITH THIS OFFERING, THE UNDERWRITERS MAY OVER-ALLOT OR EFFECT TRANSACTIONS WHICH STABILIZE OR MAINTAIN THE MARKET PRICE OF THE COMMON STOCK AT A LEVEL ABOVE THAT WHICH MIGHT OTHERWISE PREVAIL IN THE OPEN MARKET. SUCH STABILIZING, IF COMMENCED, MAY BE DISCONTINUED AT ANY TIME.

TQS Logo

TOTAL QUALITY SYSTEM o TARGETED TO THE EMERGING END-USER MARKET FOR INFECTIOUS DISEASE TEST KIT QUALITY CONTROL o USER-FRIENDLY PRODUCTS FOR MONITORING

LABORATORY PROFICIENCY, LOT ACCEPTANCE, TROUBLESHOOTING AND TRAINING

o DESIGNED TO EVALUATE THE KEY ELEMENTS IN THE TESTING PROCESS:

TEST KIT, EQUIPMENT AND PERSONNEL

o ESSENTIAL PRODUCTS IN AN

OVERALL QUALITY ASSURANCE PROGRAM

QUALITY CONTROL PRODUCTS FOR INFECTIOUS DISEASE TESTS

o SEROCONVERSION PANELS, PERFORMANCE PANELS AND SENSITIVITY PANELS FOR THE EVALUATION OF INFECTIOUS DISEASE Photograph of four of the TEST KITS Company's Quality Control Panel Products o USED BY TEST KIT MANUFACTURERS AND REGULATORS THROUGHOUT THE WORLD o DEVELOPED FROM AN EXTENSIVE INVENTORY OF HUMAN BLOOD SPECIMENS o CONTRIBUTING TO THE IMPROVED SENSITIVITY OF INFECTIOUS DISEASE TESTS WORLDWIDE

Inside Front Cover

Title at top of page reads: "Serving Our Customer's Needs Throughout the Entire Product Life Cycle."

Description of Photograph: Photograph is comprised of a pie chart superimposed over photographs of the Company's products and services. The pie chart has four sections and eight subsections. The four sections refer to the four stages in the test kit life-cycle and are captioned: "R&D," "Regulatory," "Production" and "Marketing." Each subsection has a corresponding photograph of a Company product or service. The eight subsections are captioned: "Performance Panels," "Seroconversion Panels," "Highly Characterized Specimen Bank," "Clinical Trials," "Characterized Disease State Sera," "Basematrix," "Run Controls" and "OEM and Custom Panels."

Underneath the photograph are the words: "Your Partner in Infectious Disease Quality Control" and the Company's logo is to the immediate left.

The following is qualified in its entirety by the more detailed information (including the financial statements and notes thereto) appearing elsewhere in this Prospectus. Unless otherwise indicated, all information in this Prospectus (i) assumes no exercise of the Underwriters' option to purchase from the Company up to 240,000 additional shares of Common Stock to cover over-allotments, if any, (ii) gives effect to a 1-for-2 reverse stock split with respect to the Common Stock effected in September 1996, (iii) gives effect to certain changes to the Company's Articles of Organization effected in September 1996, and (iv) gives effect to the termination of certain redemption provisions relating to 117,647 shares of Common Stock upon completion of this Offering. Unless the context indicates otherwise, all references to the "Company" are to Boston Biomedica, Inc. and its two wholly-owned subsidiaries, BTRL Contracts and Services, Inc. ("BTRL"), and BBI -- North American Clinical Laboratories, Inc. ("BBI -- NACL"). For a discussion of certain matters that should be considered by purchasers of the Common Stock offered hereby, see "Risk Factors." For the definition of certain technical and scientific terms, see "Glossary."

### THE COMPANY

Boston Biomedica, Inc. is a leading worldwide provider of proprietary quality control products for use with in vitro diagnostic test kits ("test kits") for the detection, analysis and monitoring of infectious diseases, including AIDS, Hepatitis and Lyme Disease. These products are used to develop test kits, to permit the monitoring of laboratory equipment and personnel, and to help ensure the accuracy of test results. The Company's products are derived from human plasma and serum using proprietary manufacturing processes. The Company believes its Quality Control Panel products are viewed as the current industry standard for the independent assessment of the performance of HIV and Hepatitis test kits. The Company also manufactures diagnostic test kit components and provides specialty laboratory services, including clinical trials.

To date, the Company has sold its products primarily to test kit manufacturers and regulatory agencies, but it has recently begun selling Quality Control Products directly to the emerging end-user market for quality control products for infectious disease test kits. In late 1994 the Company received United States Food and Drug Administration ("FDA") clearance for Accurun 1(R), its first Quality Control Product designed specifically for end-users, and subsequently has introduced 24 additional Accurun(tm) Quality Control Products. In July 1996, the Company introduced its Total Quality System ("TQS"), a marketing platform that combines Accurun(tm) with other Quality Control Products to provide test kit end-users with the products needed in an overall quality assurance program. TQS products allow end-users to evaluate each of the key elements of the testing process: the test kit, laboratory equipment and laboratory personnel.

The Company's customers include Abbott Diagnostics, Boehringer Mannheim, Chiron, Fujirebio, Hoffman LaRoche, Ortho Diagnostics (Johnson & Johnson) and Sanofi Diagnostics; regulatory agencies such as the United States FDA, the British Public Health Laboratory Service, the French Institut National de la Transfusion Sanguine and the German Paul Ehrlich Institute; and end-users of diagnostic test kits, such as blood banks, hospitals and clinical laboratories. The Company's products are sold to its customers pursuant to purchase orders for discrete purchases and not pursuant to long-term contracts.

The increased threat of infectious diseases has created a large and growing market for infectious disease test kits. Venture Planning Group, a medical products research firm, estimates that the worldwide infectious disease test kit market was approximately \$2.7 billion in 1995 and will grow to \$5.0 billion by 2000. The related market for quality control products for in vitro diagnostic testing for infectious and non-infectious disease totaled approximately \$600 million in 1994, according to the Genesis Report Dx, a medical products survey. The Company believes that quality control products for infectious disease test kits currently represent less than five percent of the overall quality control market, primarily as a result of the limited use of such products by end-users.

The Company believes that the market for quality control products for infectious disease test kits will continue to expand, particularly among

end-users, primarily as a result of several key factors: (i) increased regulatory scrutiny due to public concern about the dangers of infectious diseases such as AIDS and Hepatitis; (ii) growing recognition of the value of using quality control products to ensure the greatest possible safety of the blood supply, to achieve the earliest possible diagnosis of infection, and to minimize the occurrence of false negative results; (iii) the discovery of new infectious diseases and the development of new treatments for diseases requiring periodic monitoring, such as viral load testing for HIV, Hepatitis B and C and other diseases; and (iv) the emergence of new testing technologies and equipment.

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The Company offers three product groups in infectious disease diagnostics: Quality Control Panels, Accurun(tm) Run Controls and Diagnostic Components. These 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 detect the correct analyte (specificity), detect it the same way every time (reproducibility), and detect it at the appropriate levels (sensitivity). The Company's Accurun(tm) 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.

The Company's specialty clinical laboratory services include both routine and sophisticated infectious disease testing in microbiology, immunology and molecular biology. The Company seeks to focus its specialty laboratory services in advanced areas of infectious disease testing, and provides contract research and clinical trials for domestic and foreign test kit manufacturers.

The Company's strategy is to leverage its scientific capabilities in microbiology, immunology, virology, and molecular biology to (i) capitalize on the emerging end-user market, (ii) develop new products and services, (iii) enhance technical leadership, (iv) capitalize on complementary business operations, and (v) pursue strategic acquisitions and alliances.

The Company believes that it has several competitive advantages that will help it implement its strategy:

- o an inventory of approximately 50,000 distinct human blood specimens accumulated since 1986 through its worldwide sources of blood-supply, which enable the Company to quickly respond to market trends;
- o the ability to offer specialty laboratory services and conduct clinical trials, which helps it to maintain contact and enhance credibility with test kit manufacturers and regulatory authorities, and allows the Company to remain at the forefront of market trends and customer needs:
- o proprietary manufacturing know-how resulting from ten years of experience working with leading worldwide manufacturers in the development of their infectious disease test kits; and
- o its reputation as an authority in infectious disease quality control products among test kit manufacturers and regulatory agencies.

The Company, a Massachusetts corporation, was organized in 1978, but did not commence significant operations until 1986. The Company's principal offices are located at 375 West Street, West Bridgewater, MA 02379, and its telephone number is (508) 580-1900.

## THE OFFERING

Common Stock Offered

1,600,000 shares(1)

Common Stock to be Outstanding after the Offering 4,290,064 shares(1)(2)

Use of Proceeds

Repayment of indebtedness, capital expenditures, and general corporate purposes, including working capital and potential acquisitions. See "Use of Proceeds."

Proposed Nasdaq National

Market Symbol

BBII

- (1) Does not include up to 240,000 shares of Common Stock that may be sold by the Company pursuant to the Underwriters' over-allotment option. See "Underwriting."
- (2) Does not include 1,161,057 shares of Common Stock issuable upon exercise of outstanding options and warrants and 14,333 shares of Common Stock issuable upon conversion of an outstanding subordinated convertible note. See "Capitalization" and Notes 6, 10 and 11 of Notes to Consolidated Financial Statements.

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# SUMMARY CONSOLIDATED FINANCIAL DATA (In thousands, except per share data)

<TABLE> <CAPTION>

	YEAR ENDED DECEMBER 31, SIX MONTHS ENDED JUNE 30,
	1993(1) 1994 1995 1995 1996
<\$>	<c> <c> <c> <c> <c> <c> <c></c></c></c></c></c></c></c>
STATEMENT OF OPERATIONS DATA:	
Product sales	\$3,942 \$5,982 \$6,622 \$3,024 \$3,946
Service revenue	5,215 4,741 5,649 2,540 2,982
Total revenue	9,157 10,723 12,271 5,564 6,928
Income from operations	312 405 508 104 307
Net income (loss)	142 97 103 (36) 83
Net income (loss) per share(2)(3)	\$ 0.06 \$ 0.04 \$ 0.04 \$ (0.01) \$ 0.03
Weighted average common and common ed	quivalent shares
outstanding(2)(3)	2,438 2,587 3,151 2,598 3,253

  |<TABLE> <CAPTION>

JUNE 30, 1996 ------PRO FORMA ACTUAL AS ADJUSTED(4)

<C> <C>

<S>

BALANCE SHEET DATA:

Working capital Total assets Long term debt, less current maturities Redeemable common stock Total stockholders' equity \$ 4,497 \$ 14,300 10,047 19,360 2,798 --899 --3,332 16,831 - -----

- (1) On June 30, 1993, the Company exercised its option to pre-pay the acquisition note issued in connection with the 1992 purchase of BTRL at a discount from the balance due, resulting in an extraordinary gain of \$50,000, net of taxes of \$33,000. The 1993 net income per share before such extraordinary gain was \$0.04.
- (2) The effect of the common stock equivalents on net income per common share has been excluded from the calculation for 1993 and 1994 and the six months ended June 30, 1995 as its inclusion was antidilutive.
- (3) Pro forma supplementary earnings per share for the year ended December 31, 1995 and the six months ended June 30, 1996 were \$.09 and \$.06, respectively, based upon an assumed weighted average common and common equivalent shares outstanding of 3,600,007 and 3,701,173, respectively. In accordance with APB Opinion 15, pro forma supplementary earnings per share is presented as if the Company sold on January 1, 1995, 448,530 shares of Common Stock, representing the number of shares of Common Stock required to be sold at the assumed initial public offering price of \$9.00 per share in order for the Company to repay the average indebtedness outstanding during 1995 as if the Offering had occurred on January 1, 1995. See "Use of Proceeds" and Note 12 of Notes to Consolidated Financial Statements.
- (4) Adjusted to reflect: (i) application of the estimated net proceeds from the sale of 1,600,000 shares of Common Stock offered by the Company hereby at an assumed initial public offering price of \$9.00 per share, after deducting estimated underwriting discounts and commissions and offering expenses, and (ii) the termination of redemption provisions relating to 117,647 shares of Common Stock upon completion of this Offering.

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### RISK FACTORS

An investment in the shares of Common Stock offered hereby involves a high degree of risk. In addition to the other information in this Prospectus, the following factors should be considered carefully in evaluating the Company and its business before purchasing the shares of Common Stock offered hereby.

# UNDEVELOPED END-USER MARKET FOR QUALITY CONTROL PRODUCTS FOR INFECTIOUS DISEASE TEST KITS

The Company intends to focus its product development and sales and marketing efforts on quality control products for end-users of infectious disease test kits. Currently, most quality control products for infectious disease test kits are sold to test kit manufacturers and regulators. End-users of infectious disease test kits are currently using quality control products only to a very limited extent. See "Business -- Industry Overview." The Company's strategy is based primarily upon significant growth in sales of quality control products to the end-user market. See "Business -- Strategy." There can be no assurance that end-users of infectious disease test kits will increase their use of quality control products, or that the Company will be able to increase its sales of quality control products to such end-users. Clearance or approval by the United States Food and Drug Administration (the "FDA") will be necessary before quality control products may be sold for clinical laboratory use rather than for research purposes only. See "-- Stringent Government Regulation." If the end-user market for quality control products does not develop, or if the Company is unable to increase its sales to this market, the Company's future growth could be materially and adversely affected.

# COMPETITION

In sales of both its products and specialty laboratory services, the Company experiences substantial competition and the threat of competition from established and potential competitors, most of which have greater financial, manufacturing and marketing resources than the Company. Competition for customers is intense and depends principally on the ability to provide products of the quality and in the quantity required by customers, as well as the ability to provide sophisticated specialty laboratory services, at competitive prices. The Company currently competes against independent reference laboratories, integrated plasma collection and processing centers and manufacturers of quality controls and other Diagnostic Components. In addition, the Company understands that a leading manufacturer of quality control products for non-infectious diseases recently entered the quality control market for infectious disease test kits. There can be no assurance that other such manufacturers or other companies will not enter this market. The entrance of any of these companies into the quality control market for infectious disease test kits could have a material adverse effect on the Company, particularly its ability to achieve its strategy to capitalize on the end-user market for quality control products for infectious disease test kits. In addition, certain of the Company's products are derived from donors with rare antibody characteristics. Competition for blood specimens from such donors may increase, which may increase the cost of obtaining such specimens. There can be no assurance that such increased competition will not adversely affect the Company. See "-- Difficulty in Obtaining Certain Raw Materials" and "Business -- Competition."

#### ABILITY TO MANAGE GROWTH

The Company's future success will depend in part on its ability to manage growth as it increases its production capacity and broadens distribution of its products. To compete effectively and manage future growth, if any, the Company will be required to continue to implement and improve its operational, financial and management information systems, procedures and controls on a timely basis, and to expand, train, motivate and manage its workforce. There can be no assurance that the Company's personnel, systems, procedures and controls will be adequate to support the Company's future operations. The failure to implement new and improved existing operational, financial and management systems or to expand, train, motivate or manage employees could have a material adverse effect on the Company's business, operating results and financial condition. There can be no assurance that the Company will continue to grow or, if it does, that the Company will manage the growth successfully.

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# FLUCTUATIONS IN QUARTERLY RESULTS OF OPERATIONS

The Company's results of operations have been subject to quarterly fluctuations due to a variety of factors, including customer purchasing patterns and seasonal demand for laboratory testing services. In particular, the Company's sales of its Quality Control Products and Diagnostic Components typically have been highest in the fourth quarter and lowest in the first quarter of each fiscal year. For example, total revenue for the fourth quarter ended December 31, 1994 and 1995 were \$3.0 million and \$3.8 million compared with total revenue for the first quarter ended March 31, 1995 and 1996 of \$2.7 million and \$3.1 million. The Company believes that its customers may expend end-of-year budget surpluses in the fourth quarter, thereby causing the Company's fourth quarter product sales to be higher at the expense of first quarter product sales. In addition, demand for laboratory services tends to be somewhat higher in the third and fourth quarters of the fiscal year due to the seasonal nature of Lyme Disease testing, the Company's highest volume test. Moreover, the Company's margins for its different products and services vary, with Quality Control Products generally having the highest margins and Contract Research the lowest. Therefore, the Company's results may vary from period to period as a result of the mix of products and services and the mix among products. As a result, quarterly results of operations may not be indicative of future results of operations. Also, variations in the Company's quarterly results of operations may affect the market price of the Common Stock. See " --Volatility of Price of Common Stock" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

# RISK OF ACQUISITIONS

The Company intends to pursue strategic acquisitions to expand its core product line, strengthen its base in medical science and technology, and secure new sources of blood supply. The Company is subject to various risks associated with an acquisition strategy, including the risk that the Company will be unable to identify and attract suitable acquisition candidates or to integrate and manage any acquired business. The Company will compete for acquisition candidates with companies which have significantly greater financial and management resources than the Company. Acquisitions could place a significant burden on the Company's management and operating personnel. Implementing the Company's expansion strategy may also require significant capital resources. Capital is needed not only for acquisitions, but also for the effective integration, operation and expansion of such businesses. The Company may need to raise capital through the issuance of long-term or short-term indebtedness or the issuance of its securities in private or public transactions, which could result in dilution of existing equity positions, increased interest and amortization expense or decreased income to fund future expansion. There can be no assurance that acceptable financing for future acquisitions will be available or that the integration of future acquisitions and expansion of existing business can be achieved. See "-- Ability to Manage Growth."

### DIFFICULTY IN OBTAINING CERTAIN RAW MATERIALS

The Company manufactures its products from human plasma and serum which the Company obtains from nonprofit and commercial blood centers, primarily in the United States, but also from similar sources throughout the world. Certain of the Company's products, including its Seroconversion and Performance Panels, are comprised of unique and rare plasma specimens obtained from individuals during the short period of time when the disease markers of particular diseases are converting from negative to positive. See "Business -- Products." As a result, the quantity of any such panel is limited, so the Company must replace such panels as they sell out with another panel comprised of specimens equally unique and rare. Competition to obtain such specimens may increase, which may increase the cost of obtaining such products. There can be no assurance that the Company will continue to be successful in obtaining a steady and adequate supply of the unique and rare specimens of plasma and serum necessary for certain of its products. The inability to continue to obtain such specimens, or any significant delays in obtaining such specimens, would have a material adverse effect on the Company. See "-- Competition."

### DEPENDENCE ON KEY PERSONNEL

The Company's success depends in large part upon its ability to attract and retain highly qualified scientific and management personnel. The Company competes for such individuals with other companies, academic institutions, government entities and other organizations. There can be no

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assurance that the Company will be successful in hiring or retaining requisite personnel. The failure of the Company to recruit and retain qualified scientific and management personnel could have a material adverse effect on the Company. None of the Company's key management or scientific personnel is subject to an employment agreement with the Company. The loss of the services of any such key personnel, including Richard T. Schumacher, President and Chief Executive Officer of the Company, could have a material adverse effect on the Company. The Company maintains key person life insurance on certain of its officers, including Mr. Schumacher, on whose life the Company has \$4,750,000 of insurance, \$2,000,000 of which has been pledged to the Company's lender. See "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Liquidity and Capital Resources," "Business -- Competition" and "Management -- Directors and Executive Officers."

# DEPENDENCE ON KEY CUSTOMERS

The Company's three largest customers accounted for an aggregate of approximately 20% of the Company's revenues in 1993, 1994 and 1995 and the six months ended June 30, 1995 and 1996, although the customers were not identical in each period. In addition, the majority of the Company's revenues are based upon purchase orders. None of the Company's customers are contractually committed to make future product purchases from the Company. The loss of any major customer or a material reduction in a major customer's purchases would have a material adverse effect upon the Company.

A single U.S. government services contract accounted for approximately 7.5% and 7.3% of the Company's revenues in 1995 and the six months ended June 30, 1996. This contract is due to expire in February 1997. The Company has responded to a Request for Proposals by the United States government for a new four year contract to replace this contract. There can be no assurance that the Company's response to the Request for Proposals will be accepted by the United States government. Failure to receive the new contract would have a material adverse effect on the Company. See "Business -- Services."

### STRINGENT 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 (the "FDCA") prohibits the marketing of in vitro diagnostic products until they have been cleared or approved by the FDA, a process that is time-consuming, expensive and uncertain. Once clearance or approval is obtained, the FDA requires additional clearances or approvals for product changes that could affect the safety and effectiveness of the device, including, for example, new indications for use or changes in the design or manufacturing process. Additional clearances or approvals may also be required for changes in claims relating to uses of products. The Company's Accurun Run Controls, when marketed for diagnostic use, have been classified by the FDA as medical devices. The Company has received FDA clearance to market its Accurun 1(R) line for diagnostic purposes. An application for clearance for diagnostic use for one additional Accurun(tm) product has been submitted by the Company to the FDA, and the Company anticipates that applications for approximately 16 additional Accurun(tm) products will be prepared and submitted to the FDA by the end of 1997. There can be no assurance that the Company will obtain regulatory clearances or approvals on a timely basis, if at all, for future products, changes in existing products or changes in claims relating to uses of products. Delays in obtaining or failure to obtain requisite FDA clearances or approvals could have a material adverse effect on the Company.

All of the Company's Quality Control Products with the exception of Accurun 1(R) are marketed "for research use only," which do not require FDA premarket clearance or approval of the product, and not marketed for diagnostic purposes, which do require FDA premarket clearance or approval. The Company's labeling for 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 prior to marketing and initiate enforcement action against the Company, which could have a material adverse effect on the Company. Failure to obtain, or delays in obtaining, FDA clearances or approval would adversely affect the Company's strategy of capitalizing on the end-user market.

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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. There can be no assurance, 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.

In addition, both before and after clearance or approval, medical devices, such as Accurun 1(R), are subject to certain export and import requirements under the FDCA.

The Company is also subject to strict FDA good manufacturing practices ("GMP") regulations governing testing, control and documentation, and to other postmarketing restrictions with respect to the manufacture of the Company's medical device products. Ongoing compliance with GMP and other applicable regulatory requirements is monitored through periodic inspections by the

regulatory authorities. Failure to comply with GMP or other regulatory requirements can result, among other consequences, in the failure to obtain premarket clearances or approvals, withdrawal of clearances or approvals, total or partial suspension of product distribution, injunctions, civil penalties, recall or seizures of products, and criminal prosecution, each of which would have a material adverse effect on the Company.

Laws and regulations affecting the Company's products are in effect in many of the countries, states and other jurisdictions in which the Company markets or intends to market its products. There can be no assurance that the Company will be able to obtain any required regulatory clearances or approvals on a timely basis, or at all. Delays in receipt of or failure to obtain such clearances or approvals, or the failure to comply with regulatory requirements in these countries, states or other jurisdictions, could have a material adverse effect on the Company's business, financial condition and results of operations. See "Business -- Government Regulation."

The Company is also subject to other national, state and local laws and regulations, including those relating to the use and disposal of biohazardous, radioactive and other hazardous substances and wastes. Failure to comply with such laws and regulations could have a material adverse effect on the Company's business, financial condition and results of operations. See "Business -- Government Regulation."

### FOREIGN RESTRICTIONS ON IMPORTATION OF BLOOD DERIVATIVES

Sales outside the United States in 1993, 1994 and 1995 represented approximately 15%, 21% and 25%, respectively, of the Company's revenues for those years, and 27% in each of the six months ended June 30, 1995 and 1996. Foreign sales are primarily to Western Europe and Japan. Concern over blood safety has led to movements in a number of European and other countries to restrict the importation of blood and blood derivatives, including antibodies. Such restrictions continue to be debated and there can be no assurance that additional restrictions will not be imposed in the future. If imposed, such restrictions could have a material adverse effect on the Company's business.

## RISK OF TECHNOLOGICAL CHANGE

The infectious disease test kit industry is characterized by rapid and significant technological change and changes in customer requirements. As a result, the Company's success will be dependent upon its ability to enhance its existing products and to develop or acquire and introduce in a timely manner new products that take advantage of technological advances and respond to customer requirements. There can be no assurance that the Company will be successful in developing and marketing such new products or enhancements to the Company's existing products on a timely basis or that such products will adequately address the changing needs of the marketplace. Furthermore, rapid technological development by the Company or others may result in products or services becoming obsolete or noncompetitive before the Company recovers its investment in research, development and commercialization.

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### RISK OF BROAD MANAGEMENT DISCRETION IN APPLICATION OF PROCEEDS

A significant portion of the estimated net proceeds from this Offering will be allocated to working capital and general corporate purposes, including potential acquisitions. Accordingly, the Company will have broad discretion as to the application of the net proceeds and may allocate portions of such proceeds to uses which the Company's stockholders may not deem desirable. In October 1996, the Company entered into a License Agreement and Preferred Stock Purchase Agreement ("Purchase Agreement") with BioSeq, Inc. ("BioSeq"), an early stage biotechnology company that is developing a technology for sequencing, synthesizing and characterizing nucleic acids and proteins. See "Business -- Strategic Alliances." Under the Purchase Agreement, the Company has agreed to purchase approximately 19% of the outstanding capital stock of BioSeq for an aggregate of \$1,482,500, to be paid in three installments. The Company has paid the first installment of \$210,000 and will pay the second installment of \$522,500 upon completion of the Offering. The Company intends to use a portion of the proceeds of this Offering to fund the second installment and \$210,000 of

such proceeds to repay amounts drawn on the Company's revolving line of credit to fund the first installment. The Company must make the remaining \$750,000 installment if BioSeq attains certain technical milestones by July 31, 1997. There can be no assurance as to the commercial viability of BioSeq's technology or that the Company will not lose its entire investment in BioSeq. Additionally there can be no assurance that the Company's use of any of the proceeds from the Offering will yield any return. See "Use of Proceeds."

### PROTECTION OF INTELLECTUAL PROPERTY AND PROPRIETARY TECHNOLOGY

None of the Company's Quality Control Products or Diagnostic Components have been patented and the Company does not intend to seek patent protection for such products. The Company's ability to compete effectively with other companies will depend, in part, on its ability to maintain the proprietary nature of its technologies and products and operate without infringing the rights of third parties. The Company relies primarily on a combination of trade secrets and non-disclosure and confidentiality agreements, and in certain limited circumstances, patents, to establish and protect its proprietary rights in its technology and products. There can be no assurance that others will not independently develop or otherwise acquire the same, similar or more advanced trade secrets and know-how.

The Company has two United States patents and, jointly with the University of North Carolina at Chapel Hill ("UNC"), has filed three series of United States and foreign patent applications relating to compounds, pharmaceutical compositions and therapeutic methods in connection with the Company's drug discovery program at the University of North Carolina at Chapel Hill. See "Business -- Services," and " -- Strategic Alliances." There can be no assurance that patent applications will result in issued patents, that issued patents will provide any competitive advantage or that patents will not be challenged, circumvented or invalidated.

Third parties may be issued patents to, or may otherwise acquire the rights to, technology necessary or potentially useful to the Company. The success of the Company is dependent in part upon its not infringing patents or other intellectual property rights of third parties. Litigation relating to the infringement of the patents or other intellectual property rights of others could result in substantial costs to the Company. Litigation which could result in substantial costs to the Company may also be necessary to enforce the Company's intellectual property rights or to determine the scope and validity of the proprietary rights of others. Any such substantial costs would have a material adverse effect on the Company.

### UNCERTAINTY RELATED TO HEALTHCARE REFORM; NO ASSURANCE OF ADEQUATE REIMBURSEMENT

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental change. Although to date Congress has failed to pass comprehensive health care reform legislation, the Company anticipates that Congress and state legislatures will continue to review and assess alternative healthcare delivery and payment systems and may in the future propose and adopt legislation effecting fundamental changes in the healthcare delivery system. Legislative debate is expected to continue in the future. In addition, the private sector has been changing the healthcare industry as well through consolidations and alternatives in healthcare delivery systems. The Company cannot predict what impact the adoption of any federal or state health care reform measures or future private sector reform may have on its industry or business.

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In both domestic and foreign markets, sales by the Company's customers of products and services that incorporate or affect the demand for the Company's products may depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the price and cost- effectiveness of medical products and services. There can be no assurance that pricing pressures experienced by the Company's customers will not adversely affect the Company because of a determination that its products are not cost effective or because of inadequate third-party

reimbursement levels to such customers. In addition, where the payor for the Company's specialty laboratory services is the patient rather than third-party payors, there is a greater risk of non-payment. See "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Results of Operations."

### RISK OF HAZARDOUS WASTE AND PRODUCT LIABILITY; ABSENCE OF INSURANCE

The Company's manufacturing processes involve the controlled use of biohazardous materials and chemicals. The risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any damages that result, and any such liability could exceed the resources of the Company. The Company may incur substantial costs to maintain safety in the use of biohazardous materials and to comply with environmental regulations as the Company further develops its manufacturing capacity. See "Business -- Government Regulation."

Further, the Company's business exposes it to liability risks that are inherent in the testing, manufacturing and marketing of its products. The Company does not currently have product liability insurance. Product liability claims could expose the Company to substantial liabilities and expenses, which could materially and adversely affect the Company.

### RISKS ASSOCIATED WITH EXPORT SALES

The Company generated significant sales outside the United States and anticipates that foreign sales will continue to account for a significant percentage of the Company's net revenues. The Company's foreign operations accounted for approximately 15%, 21% and 25% of the Company's total revenues for the years ended December 31, 1993, 1994 and 1995, respectively, and approximately 27% in each of the six months ended June 30, 1995 and 1996, and 36%, 38% and 47% of the Company's product sales for the years ended December 31, 1993, 1994 and 1995, respectively, and 50% and 48% for each of the six months ended June 30, 1995 and 1996. The Company therefore is subject to risks associated with foreign sales, including United States and foreign regulatory requirements and policy changes, political and economic instability, difficulties in accounts receivable collection, difficulties in managing distributors or representatives and seasonality of sales. Although the Company's sales have been denominated in United States dollars, the value of the United States dollar in relation to foreign currencies may also adversely affect the Company's sales to foreign customers. To the extent that the Company expands its international operations or changes its pricing practices to denominate prices in foreign currencies, the Company will be exposed to increased risks of currency fluctuation. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Note 5 of Notes to Consolidated Financial Statements.

# POSSIBLE ADVERSE EFFECT OF CONTROL BY EXISTING STOCKHOLDERS

Upon consummation of this Offering, Richard T. Schumacher, President and Chief Executive Officer, his relatives and the existing officers and directors of the Company collectively will have voting control over approximately 39% of the outstanding shares of Common Stock. Accordingly, these stockholders, should they choose to act in concert, will be in a position to exercise a significant degree of control over the Company, and to significantly influence stockholder votes on the election of the Company's directors, increasing the Company's authorized capital stock, mergers, and sales of the Company's assets. See "Principal Stockholders."

### POSSIBLE ADVERSE EFFECT OF CERTAIN ANTI-TAKEOVER PROVISIONS

Certain provisions of the Company's Amended and Restated Articles of Organization and Restated Bylaws could have the effect of discouraging a third party from pursuing a non-negotiated takeover of the Company and preventing certain changes in control. These provisions include a classified Board of Directors, a fair price provision, advance notice to the Board of Directors of stockholder proposals and

stockholder nominees for the Board of Directors, limitations on the ability of stockholders to remove directors and call stockholders meetings, the provision that vacancies on the Board of Directors be filled by a majority of the remaining directors and the ability of the Board to issue, without further stockholder approval, preferred stock with rights and privileges which could be senior to the Common Stock. The Company also is subject to Chapter 110F of the Massachusetts General Laws which, subject to certain exceptions, prohibits a Massachusetts corporation from engaging in any of a broad range of business combinations with any "interested stockholder" for a period of three years following the date that such stockholder became an interested stockholder. These provisions could discourage a third party from pursuing a takeover of the Company at a price considered attractive by many stockholders, since such provisions could have the effect of preventing or delaying a potential acquiror from acquiring control of the Company and its Board of Directors. See "Description of Capital Stock -- Preferred Stock." "-- Massachusetts Anti-Takeover and Related Statutes" and " -- Certain Provisions of the Company's Articles of Organization and By-laws."

# NO ASSURANCE OF PUBLIC MARKET; POSSIBLE VOLATILITY OF PRICE OF COMMON STOCK

Prior to this Offering, there has been no public trading market for the Common Stock. There can be no assurance that a regular trading market for the Common Stock will develop after this Offering or that, if developed, it will be sustained. The initial public offering price of the Common Stock will be determined by negotiations between the Company and Representatives of the Underwriters and may not be indicative of the price at which the Common Stock will trade after completion of this Offering. For factors that will be considered in determining the initial public offering price, see "Underwriting." After completion of this Offering, the market price of the Common Stock could be subject to significant fluctuations in response to various factors and events, including the liquidity of the market for the shares of Common Stock, variations in the Company's operating results, changes in earnings estimates by securities analysts, publicity regarding the Company, the infectious disease test kit industry or the healthcare industry generally, new statutes or regulations or changes in the interpretation of existing statutes or regulations affecting the healthcare industry in general or the infectious disease test kit industry in particular. In addition, the stock market in recent years has experienced broad price and volume fluctuations that often have been unrelated to the operating performance of particular companies. These market fluctuations also may adversely affect the market price of the shares of Common Stock.

# LACK OF UNDERWRITING HISTORY

Kaufman Bros., L.P. became registered as a broker-dealer in July 1995 and has participated in a limited number of public offerings as an underwriter. As part of its due diligence function, the Underwriters make such inquiries of management as they deem appropriate, review the accuracy of the Prospectus and establish the initial public offering price for the Common Stock. Prospective purchasers of Common Stock offered hereby should consider the limited experience of Kaufman Bros., L.P. in evaluating an investment in the Common Stock. See "Underwriting."

### DILUTION

Purchasers of shares in the Offering will suffer immediate dilution of \$5.10 in net tangible book value per share. See "Dilution" and "Underwriting."

# SHARES ELIGIBLE FOR FUTURE SALE

Sales of substantial amounts of Common Stock in the public market, or the perception that such sales may occur, could adversely affect the prevailing market price of the Common Stock and the ability of the Company to raise capital through a public offering of its equity securities. Upon completion of this Offering, the Company will have 4,290,064 shares of Common Stock outstanding

(4,530,064 shares if the Underwriters' overallotment option is exercised in full). Of those shares, the 1,600,000 shares sold in this Offering (1,840,000 shares if the Underwriters' overallotment option is exercised in full) will be freely tradeable without restriction (except as to affiliates of the Company) or further registration under the Securities Act. All of the Company's directors and executive officers and certain other stockholders, holding in the

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aggregate 2,555,244 shares of Common Stock, have agreed not to offer to sell, sell or otherwise dispose of any shares of Common Stock prior to the expiration of 180 days from the date of this Prospectus. Oscar Gruss & Son Incorporated may, in its sole discretion and at any time without prior notice, release all or any portion of the shares of Common Stock subject to the lockup agreements. Beginning 91 days after the date of this Prospectus, 6,475 shares of Common Stock will be eligible for sale in the public market without registration, subject to certain volume and other limitations, pursuant to Rule 144 or Rule 701 under the Securities Act of 1933, as amended (the "Securities Act") and an additional 122,571 shares will be eligible for sale without such restrictions. Following the expiration of the 180-day lockup period, an additional 1.643.197 shares of Common Stock will be eligible for sale in the public market without registration, subject to certain volume and other limitations, pursuant to Rule 144 or Rule 701 under the Securities Act and an additional 734,425 shares will be eligible for sale without such restrictions. The remaining shares of Common Stock held by existing stockholders, including shares issuable upon exercise of options, will become eligible for sale under Rule 144 or otherwise at various times thereafter. All shares of Common Stock outstanding on the date of this Prospectus will be eligible for sale to certain qualified institutional buyers in accordance with Rule 144A under the Securities Act. The Company intends to register under the Securities Act, shortly after the consummation of the Offering, shares of Common Stock issuable upon exercise of employee stock options, including 934,387 shares issuable upon exercise of such options outstanding on the date of this Prospectus. Two of the Company's stockholders and the holder of a warrant to purchase Common Stock have the right to cause the Company to register their shares under the Securities Act and to include their shares in certain future registrations of securities effected by the Company under the Securities Act. An aggregate of 627,650 shares of Common Stock, including 226,670 shares of Common Stock issuable upon exercise of outstanding warrants, are covered by such registration rights. If such holders, by exercising their registration rights, cause a large number of shares to be registered and sold in the public market, such sales may have an adverse effect on the market price of the Common Stock. If the Company is required to include in a Company-initiated registration shares held by such holders pursuant to the exercise of their piggyback registration rights, such sales may have an adverse effect on the Company's ability to raise needed capital. See "Certain Transactions," "Principal Stockholders" and "Shares Eligible for Future Sale."

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### USE OF PROCEEDS

The net proceeds to be received by the Company from the sale of the 1,600,000 shares of Common Stock offered hereby are estimated to be \$12,600,000 (\$14,587,200 if the Underwriters over-allotment option is exercised in full), at an assumed public offering price of \$9.00 per share and after deducting estimated underwriting discounts and commissions and offering expenses payable by the Company.

The Company expects to use approximately \$4.1 million of the net proceeds to repay outstanding indebtedness, as described below, and approximately \$1.0 million for capital expenditures to expand its manufacturing capacity in West Bridgewater, of which approximately \$500,000 will be spent on building expansion and approximately \$500,000 will be spent on equipment. The Company intends to use \$522,500 of the net proceeds of this Offering to fund the second installment of its investment in BioSeq. The Company anticipates using the remaining net

proceeds for general corporate purposes, including working capital, as well as for potential acquisitions and alliances. See "Risk Factors -- Risk of Broad Management Discretion in Application of Proceeds," and "Business -- Strategic Alliances."

At October 23, 1996, the approximately \$4.1 million of indebtedness to be repaid from the proceeds of this Offering consists of (i) approximately \$2.4 million of indebtedness under a secured revolving line of credit due June 30, 1998 that bears interest at a rate equal to the prime rate plus 0.5% per annum; (ii) a mortgage note in the principal amount of approximately \$678,225 on the West Bridgewater property that bears interest at a fixed rate of 8.3% per annum until December 2000 and thereafter bears interest at a rate equal to the prime rate plus 1% per annum, and which is due December 2002; (iii) a term note, in the principal amount of \$424,500, that bears interest at 9.01% per annum and is due in October 1998; (iv) a term note, in the principal amount of \$133,333, that bears interest at the prime rate plus 1% per annum and is due October 1999; (v) a term note, in the principal amount of \$315.686, that bears interest at a rate equal to the prime plus 1% per annum and is due August 2000; (vi) a term note, in the principal amount of \$85,000, that bears interest at a rate of 8.22% per annum and is due December 2000; and (vii) various other notes that aggregate \$77,459 due from June 1997 to August 2000. The proceeds from borrowings incurred within the past year were used for working capital, to acquire the West Bridgewater property, to purchase capital equipment and to make the Company's \$210,000 initial investment in BioSeq. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Note 6 of Notes to the Consolidated Financial Statements.

With respect to potential acquisitions and alliances, in addition to the investment in BioSeq, the Company may use a portion of the net proceeds to acquire blood donor centers and other businesses, products or technologies that are complementary to the Company's current business, although it currently has no commitments for such acquisitions or alliances. See "Business -- Strategy."

The specific timing and amount of funds required for specific uses by the Company cannot be precisely determined at this time. Pending such uses, the Company intends to invest in short-term, investment grade, interest bearing obligations.

### DIVIDEND POLICY

The Company has never declared or paid cash dividends on its capital stock and does not plan to pay any cash dividends in the foreseeable future. The Company's current policy is to retain all of its earnings to finance future growth. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon the Company's financial condition, operating results, capital requirements, general business conditions and such other factors as the Board of Directors deems relevant. The Company is subject to financial and operating covenants, including a prohibition against the payment of cash dividends, under its bank financing agreement. See "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Liquidity and Capital Resources."

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### **CAPITALIZATION**

The following table sets forth as of June 30, 1996 (i) the actual capitalization of the Company, (ii) the pro forma capitalization of the Company after giving effect to the termination of certain redemption provisions relating to 117,647 shares of Common Stock, and (iii) as adjusted to give effect to the sale of 1,600,000 shares of Common Stock offered by the Company hereby at an assumed public offering price of \$9.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by the Company. This table should be read in conjunction with the Consolidated Financial Statements and related notes thereto appearing elsewhere in this Prospectus.

# JUNE 30, 1996

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# PRO FORMA ACTUAL PRO FORMA AS ADJUSTED

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# (IN THOUSANDS, EXCEPT SHARE DATA)

<\$>	<c> <c> <c></c></c></c>
Current maturities of long term debt	\$ 490  \$ 490  \$
	=======================================
Long-term debt, less current maturitie	es:
Line of credit	1,398 1,398
Bank term debt	719 719
Mortgage term debt	620 620
Other notes payable	61 61
	2,798 2,798
Redeemable common stock, \$.01 parties issued and outstanding 117,647, and and pro forma as adjusted	
•	
Stockholders' equity:	
Common stock, \$.01 par value; as	uthorized
15,000,000 shares; issued and out	tstanding
2,572,417 actual, 2,690,064 pro for	rma and
4,290,064 pro forma as adjusted(1)	) 26 27 43
Preferred Stock	
Additional paid-in capital	2,717 3,615 16,199
Retained earnings	589 589 589
Total stockholders' equity	3,332 4,231 16,831
Total capitalization	\$7,029 \$7,029 \$16,831

</TABLE>

(1) Excludes the following at June 30, 1996: (i) 934,387 shares of Common Stock issuable pursuant to the exercise of stock options outstanding at a weighted average exercise price of \$3.15 per share, of which options to purchase 653,684 shares were then exercisable, (ii) 226,670 shares of Common Stock issuable pursuant to the exercise of warrants outstanding at a weighted average exercise price of \$2.50 per share, all of which were then exercisable, and (iii) 14,333 shares of Common Stock issuable upon conversion of the subordinated convertible note at \$1.50 per share. Since June 30, 1996, no stock options were exercised, granted or became exercisable. See "MANAGEMENT -- Stock Plans."

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# DILUTION

At June 30, 1996, the Company had a net tangible book value of \$4,137,943 or \$1.54 per share of Common Stock. "Net tangible book value per share" represents the tangible book value of the Company (total tangible assets less total liabilities) divided by the number of shares of Common Stock outstanding (on a pro forma basis to give effect to the termination of certain redemption provisions relating to 117,647 shares of Common Stock). Without taking into account any changes in such net tangible book value as of June 30, 1996, other

than to give effect to the sale by the Company of the 1,600,000 shares of Common Stock offered hereby at an assumed initial public offering price of \$9.00 and after deducting the estimated underwriting discounts and commissions and offering expenses payable by the Company, the pro forma net tangible book value of the Company at June 30, 1996 would have been \$16,737,943, or \$3.90 per share. This represents an immediate increase in the net tangible book value per share of \$2.36 to existing stockholders and an immediate dilution of the net tangible book value per share of \$5.10 to persons purchasing the Common Stock offered hereby (the "New Investors"). The following table illustrates this per share dilution:

Assumed initial public offering price per share \$9.00

Net tangible book value per share before the Offering \$1.54

Increase per share attributable to New Investors 2.36

Pro forma as adjusted net tangible book value per share after the Offering 3.90

Dilution per share to New Investors \$5.10

The following table sets forth on a pro forma basis, as of June 30, 1996, the total number of shares purchased from the Company after giving effect to the sale of the 1,600,000 shares of Common Stock offered by the Company hereby, the total consideration paid to the Company and the average price per share paid by existing stockholders and by New Investors at an assumed initial public offering price of \$9.00 per share:

<TABLE> <CAPTION>

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The above information assumes (i) no exercise of the Underwriters' warrants and (ii) no exercise of any other outstanding options and warrants after June 30, 1996. As of June 30, 1996, there were outstanding options, warrants and a subordinated convertible note to purchase an aggregate of 1,175,390 shares of Common Stock at exercise prices ranging from \$0.25 to \$8.50 per share. Since June 30, 1996, no stock options were exercised, granted or became exercisable. To the extent these options and warrants are exercised, there will be further dilution to New Investors. See "Management -- Stock Plans," "Certain Transactions" and Note 10 of Notes to Consolidated Financial Statements.

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# SELECTED CONSOLIDATED FINANCIAL DATA

The following table contains certain selected consolidated financial data of the Company and is qualified in its entirety by the more detailed Consolidated Financial Statements and Notes thereto included elsewhere in this Prospectus. The statement of operations data for the fiscal years 1993, 1994 and 1995, and the balance sheet data as of December 31, 1994 and 1995, have been derived from the Consolidated Financial Statements of the Company which have been audited by Coopers & Lybrand L.L.P., independent accountants, and which appear elsewhere in

this Prospectus. The balance sheet data as of December 31, 1993 are derived from consolidated financial statements that have been audited by Coopers & Lybrand L.L.P. The statement of operations data of the Company for the fiscal years ending December 31, 1991 and 1992 and the balance sheet data as of December 31, 1991 and 1992 have been derived from consolidated financial statements of the Company which have been audited by other independent public accountants. The unaudited consolidated financial data as of June 30, 1996, and for the six months ended June 30, 1996 and 1995, have been prepared on a basis consistent with the audited consolidated financial statements and, in the opinion of management, include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the financial condition and results of operations for the periods presented. The results for the six months ended June 30, 1996, are not necessarily indicative of the results that may be expected for the year ending December 31, 1996. This data should be read in conjunction with the Consolidated Financial Statements and related Notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere herein.

<TABLE> <CAPTION>

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#### SIX MONTHS ENDED

\$3,946

6,928

2,007

362 915 1,088

6,622

YEAR ENDED DECEMBER 31. JUNE 30, JUNE 30, 1991 1992(1) 1993(2)(3) 1994 1995 1995 1996 (IN THOUSANDS, EXCEPT PER SHARE DATA) <C> <C> <C> <C> <C> <C> <C> CONSOLIDATED STATEMENT OF OPERATIONS DATA:

REVENUE:							
Product sales	32,146	\$2,955	\$3,942	\$ 5,982	\$ 6,622	\$3,024	4 \$ 3,9
Services	264 1,6	580 5	,215 4,	,741 5,6	549 2,5	540 2	,982
Total revenue	2,410	4,635	9,157	10,723	12,271 	5,564	6,928
COSTS AND EXPENSES:							
Cost of product sales	1,172	1,638	2,088	3,194	3,564	1,646	2,00
Cost of services	191	1,443	3,965	3,416	4,168	1,960	2,250
Research and development	1	04 22	22 279	9 46	9 375	159	36
Selling and marketing	372	353	894	1,192	1,340	638	915
General and administrative	43	6 745	1,619	2,04	7 2,31	6 1,05	7 1,0
Total operating costs and expense	es 2	2,275 4	,401 8	,845 1	0,318	11,763	5,460
Income from operations	13:	5 234	312	405	508	104	306
Interest expense, net	101	113	179	244	336	164	168
Income (loss) before income taxes	and						

Income (loss) before income taxes and (60)34 121 133 161 138 extraordinary item 172 (69) (64) Provision for income taxes (5) (45) (41) 24 (55)Income (loss) before extraordinary item 92 76 103 (36)Extraordinary item-gain on elimination of debt, net of income taxes 50 ----\$ 29 \$ 76 \$ 97 \$ 103 \$ (36) \$ 83 Net income (loss) \$ 142

\$ 0.01 \$ 0.04 Net income (loss) per share(4)(5)\$ 0.06 \$ 0.04 \$ 0.04 \$(0.01) \$ 0.03 Weighted average common and common equivalent

shares outstanding(4)(5)1,948 2,160 2,438 2,587 3,151 2,598

1991

</TABLE>

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<TABLE> <CAPTION>

> DECEMBER 31. JUNE 30, 1996 1993 1994 1995 ACTUAL PRO FORMA(7)

### --- --- --- --- ----

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# CONSOLIDATED BALANCE SHEET DATA:

Working capital(6) \$1,698 \$2,457 \$3,612 \$4,686 \$4,829 \$4,497 \$4,497 Total assets 2,624 4,828 6,870 8,076 9,928 10,047 10,047

Long term debt, less current maturities(6) 993 1,760 2,381 3,180 4,216 2,798 2,798

Redeemable common stock -- -- 899 --

Total stockholders' equity 993 1,837 2,762 3,041 3,187 3,332 4,231

Dividends -- None

</TABLE>

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- (1) Effective July 1, 1992, the Company acquired through its BTRL subsidiary the net assets of a division of Cambridge Biotech Corporation for \$762,000 which increased 1992 revenues by \$1,450,000.
- (2) On June 30, 1993, the Company exercised its option to pre-pay the acquisition note in connection with the 1992 purchase of BTRL at a substantial discount from the balance due, resulting in an extraordinary gain of \$50,000 net taxes of \$33,000. The 1993 net income per share before such extraordinary gain was \$0.04.
- (3) Effective January 1, 1993, the Company acquired the net assets of North American Laboratory Group Ltd., Inc. for \$425,000, which increased 1993 revenues by \$2,019,000.
- (4) The effect of the common stock equivalents on net income per share has been excluded from the calculation for years ended December 31, 1991 through 1994 and the six months ended June 30, 1995 as its inclusion was antidilutive.
- (5) Pro forma supplementary earnings per share for the year ended December 31, 1995 and the six months ended June 30, 1996 were \$.09 and \$.06, respectively, based upon an assumed weighted average common and common equivalent shares outstanding of 3,600,007 and 3,701,173, respectively. In accordance with APB Opinion 15, pro forma supplementary earnings per share is presented as if the Company sold on January 1, 1995, 448,530 shares of Common Stock, representing the number of shares of Common Stock required to be sold at the assumed initial public offering price of \$9.00 per share in order for the Company to repay the average indebtedness outstanding during 1995 as if the Offering had occurred on January 1, 1995. See "Use of Proceeds" and Note 12 of Notes to Consolidated Financial Statements.
- (6) The Company's demand line of credit with outstanding amounts of \$880,000, \$1,091,000 and \$1,895,000 as of December 31, 1991, 1992 and 1993, respectively, has been presented as part of long-term debt (and excluded from current liabilities in calculating working capital) for 1991 through 1993 to be consistent with its reclassification to long-term debt in 1994, 1995 and 1996 due to a modification of its maturity date.
- (7) Adjusted to reflect the reclassification of Redeemable Common Stock into 117,647 shares of Common Stock upon completion of this Offering, thereby terminating the redemption provisions.

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

This Prospectus contains forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in "Risk Factors."

The following discussion and analysis should be read in conjunction with the Company's Consolidated Financial Statements and the Notes thereto appearing elsewhere in this Prospectus.

#### **OVERVIEW**

The Company generates revenue from products and services provided to the in vitro diagnostic infectious disease industry. Products consist of three groups: Quality Control Panels, Accurun(tm) Run Controls and Diagnostic Components. Services consist of Specialty Clinical Laboratory Testing, Contract Research, Clinical Trials and Drug Screening. In the three full years since the Company's acquisition of BTRL and BBI-NACL, the Company has experienced a shift in revenue mix towards increased product sales, as product revenue as a percentage of total revenue increased from 43.1% in 1993 to 54.0% in 1995, with a corresponding decrease in the percentage of total revenue provided by services.

The Company's gross profit margin increased from 33.9% in 1993 to 37.0% in 1995 principally as a result of the increased percentage of higher margin product revenues. Within products, the Company's Quality Control Products (Accurun(tm) Run Controls and Quality Control Panels) have higher margins than the Company's Diagnostic Components. Within services, Contract Research gross margins are lower than other services. However, such contracts enable the Company to maintain certain scientific staff and capability that it might otherwise not be able to afford. The Company intends to continue to concentrate on the growth in sales of its Quality Control Products.

Historically, the Company's results of operations have been subject to quarterly fluctuations due to a variety of factors, including customer purchasing patterns, primarily driven by end-of-year expenditures, and seasonal demand during the summer months for certain laboratory testing services. In particular, the Company's sales of its 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 Specialty Clinical Laboratory Testing has generally reached a seasonal peak during the third quarter, coinciding with the peak incidence of Lyme Disease. Research Contracts are generally for large dollar amounts spread over a one or two year period, and upon completion, frequently do not have renewal phases. As a result they 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. See "Risk Factors -- Fluctuations in Quarterly Results of Operations."

To develop new Quality Control Products and support increased sales, the Company hired additional research and development staff in the second half of 1995 and sales and marketing staff in 1996. The Company intends to continue to add staff to these departments. This should cause both research and development and selling and marketing expenses to increase as a percentage of revenue in 1996 and 1997, compared to 1995. General and administrative expenses are not expected to increase at the same rate, as the Company has already incurred significant infrastructure expenses.

The Company does not have any foreign operations. However, the Company does have significant export sales to agents under distribution agreements, as well as directly to test kit manufacturers. All sales are denominated in U.S. dollars. Export sales for the years ended December 31, 1993, 1994, and 1995 were \$1.4 million, \$2.3 million, and \$3.1 million, respectively, and for the six months ended June 30, 1995 and 1996 were \$1.5 million and \$1.9 million, respectively. The Company expects that export sales will continue to be a significant source of revenue and operating income. See "Risk Factors -- Risks Associated with Export Sales."

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The Company's cash flow from operations over the last three years has been negative as it funded investment in research and development, increased sales and marketing expenditures, and supported growth-driven working capital needs. The Company funded the shortfall through a combination of sales of common stock

and bank financing. The Company anticipates using a portion of the net proceeds of this Offering for working capital requirements until such time as its cash flow from operations becomes sufficient.

#### RESULTS OF OPERATIONS

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

<TABLE> <CAPTION> YEAR ENDED SIX MONTHS DECEMBER 31, ENDED JUNE 30, 1993 1994 1995 1995 1996 <S> <C> <C> <C> <C> Revenue: **Products** 43.1% 55.8% 54.0% 54.4% 57.0% 56.9 44.2 46.0 45.6 43.0 Services 100.0 100.0 100.0 100.0 100.0 Total revenue Gross profit 33.9 38.4 37.0 35.2 38.6 Operating expenses: Research and development 3.0 4.4 3.1 2.9 Selling and marketing 9.8 11.1 10.9 11.4 13.2 General and administrative 17.7 19.1 18.9 19.0 15.7 Total operating expenses 30.5 34.6 32.9 33.3 34.1 Income from operations 3.4 3.8 4.1 1.9 4.4 2.3 2.7 Interest expense 2.0 3.0 2.4 Income (loss) before income taxes 1.5 1.5 1.4 (1.1) 2.0 Net income (loss) 1.6 0.9 0.8 (0.6) 1.2 Product gross profit 47.0% 46.6% 46.2% 45.6% 49.1% Services gross profit 24.0% 28.0% 26.2% 22.8% 24.6% </TABLE>

# SIX MONTHS ENDED JUNE 30, 1996 AND 1995

Total revenue increased 24.5%, or \$1,364,000, to \$6,928,000 for the six months ended June 30, 1996 from \$5,564,000 in the prior year period. This increase was the result of an increase in product sales of 30.4%, or \$921,000, to \$3,946,000 from \$3,025,000 and an increase in specialty laboratory services of 17.4%, or \$443,000, to \$2,983,000 from \$2,540,000. Product revenue increased primarily as a result of an overall increase of 34.5% in Quality Control Products, due to sales of new products and increased volume of existing products, including an increase of 132.5% in the sales of Accurun(tm). The increase in service revenue was primarily attributable to a 19.0% increase in Specialty Clinical Laboratory Testing revenue, particularly molecular (PCR) testing, and the addition of two new research contracts with the National Institutes of Health in the fourth quarter of 1995.

Gross profit increased 36.5%, or \$714,000, to \$2,672,000 for the six months ended June 30, 1996 from \$1,958,000 in the prior year period. The gross profit margin increased to 38.6% in the six months ended June 30, 1996 versus 35.2% in the prior year period. Gross margins improved in both products, (45.6% to 49.1%), and services (22.8% to 24.6%), as the Company benefited from an improved revenue mix at the higher volume level.

Research and development expenses increased 127.4%, or \$203,000, to \$362,000 for the six months ended June 30, 1996 from \$159,000 in the prior year period. Research and development costs as a percentage of revenues increased to 5.2% for the six months ended June 30, 1996 from 2.9% in the comparable 1995 period. This increase was primarily the result of increased costs of personnel hired in the second half of 1995 which enabled the Company to introduce over 30 new products in the first half of 1996 compared with 15 new introductions in the prior year period.

increase was primarily attributable to increased personnel costs associated with the addition of tele-sales staff for Quality Control Products, particularly Accurun(tm), and increased advertising costs due to the commencement of the Company's "Total Quality System" (TQS) marketing campaign.

General and administrative expenses increased 3.0%, or \$31,000, to \$1,088,000 for the six months ended June 30, 1996 from \$1,057,000 in the prior year period. As a result, general and administrative expenses decreased as a percentage of revenues to 15.7% for 1996 from 19.0% in the prior year period as management maintained close control of expense levels.

Interest expense was essentially unchanged in the six months ended June 30, 1996 versus the prior year period as the prime rate increases in late 1995 were offset by reduced borrowing due to both additional equity raised and prepayments from certain customers for contract research services.

### YEARS ENDED DECEMBER 31, 1995 AND 1994

Total revenue increased 14.4%, or \$1,548,000, to \$12,271,000 in 1995 from \$10,723,000 in 1994. The increase in revenues was the result of a 10.7% increase in product revenues of \$640,000 to \$6,622,000 from \$5,981,000, and a 19.1% increase in service revenues of \$908,000 to \$5,649,000 from \$4,741,000 in 1995 compared to 1994. The increase in product revenue was attributable to an increase in prices at the beginning of 1995 and an increase in the volume of sales of Quality Control Products and Basematrix (part of the Diagnostic Components group), which increase was partially offset by the absence of revenues in 1995 from two OEM Quality Control Panel contracts which were completed in 1994. The Company also reduced emphasis on certain lower margin Diagnostic Components as it focused more effort on sales of its proprietary Basematrix product, which carries a higher margin. During 1995, the Company reorganized its sales and marketing department and believes that this had an adverse effect on sales growth for the period. The increase in service revenue was primarily the result of increased specialty clinical laboratory testing, two new research contracts and increased clinical trial services, particularly in the area of HIV.

Gross profit increased 10.4%, or \$426,000, to \$4,539,000 for 1995 from \$4,113,000 in 1994. Products gross profit increased 9.7%, or \$270,000, to \$3,057,000 in 1995 from \$2,787,000 in 1994 as the products sales increase was offset by a small decrease in products gross profit margin (to 46.2% in 1995 from 46.6%). The products gross margin decrease was a result of a small increase in material handling personnel costs. Services gross profit increased 11.8%, or \$156,000, to \$1,481,000 in 1995 from \$1,326,000 in 1994 as the sales increase was offset by a decrease in services gross profit margin to 26.2% in 1995 from 28.0% in 1994. Services gross margin declined primarily as a result of increased personnel costs in the specialty clinical laboratory and an increase in contract research activities, which carry a lower margin.

Research and development expenditures decreased 20.0%, or \$94,000, to \$376,000 in 1995 from \$469,000 in 1994. The decrease resulted from certain technical staff being utilized for Company sponsored research and development in 1994 and Contract Research in 1995. See "-- Years Ended December 31, 1994 and 1993." Development projects included Accurun(tm), molecular and immunological Run Controls, specialized molecular assays, and the development of a second generation Lyme Disease western blot test kit for internal use by the Company's specialty testing laboratory.

Selling and marketing expenses increased 12.4%, or \$148,000, to \$1,340,000 in 1995 from \$1,192,000 in 1994. The increase was primarily attributable to additional sales and marketing staff and overhead, partially offset by lower trade show and travel expenses as the Company realized greater benefits from its distributor network.

General and administrative costs increased 13.1%, or \$269,000, to \$2,316,000 in 1995 from \$2,047,000 in 1994. This increase was primarily attributable to additional staffing in support of revenue growth and higher reserve provisions for doubtful accounts associated with the increased volume of revenue related to testing in situations where payment to the Company depends on collecting from the

patient rather than a healthcare institution. These increases were partially offset by lower professional fees. Also included in general and administrative expense was approximately \$60,000 of nonrecurring costs associated with the move of the specialty testing laboratory into a larger, custom-designed facility.

Interest expense increased 37.8%, or \$92,000, to \$336,000 in 1995 from \$244,000 in 1994, as the Company funded its working capital needs primarily through increased borrowings.

### YEARS ENDED DECEMBER 31, 1994 AND 1993

Total revenue increased 17.1%, or \$1,566,000, to \$10,723,000 in 1994 from \$9,157,000 in 1993. This increase was a result of a 51.7%, or \$2,039,000, increase in product sales, partially offset by a 9.1%, or \$473,000, decrease in service revenue. The product sales increase was primarily attributable to unit volume growth of both existing and new Quality Control Panels for HIV and HCV, and, to a lesser extent, to sales of the Company's first molecular-based Quality Control Panel targeted for end-user PCR training. The service revenue decline was primarily attributable to the completion in February 1994 of a government contract with the United States Army for retrovirology research that reduced contract research revenue by approximately \$1,100,000 in 1994 compared with 1993. This decrease was partially offset by a \$676,000, or 36.5%, increase in specialty laboratory testing services.

Gross profit increased 32.5%, or \$1,009,000, to \$4,113,000 for 1994 from \$3,104,000 in 1993. Products gross profit increased 50.3%, or \$933,000, to \$2,787,000 in 1994 from \$1,855,000 in 1993 as the products sales increase was partially offset by a small decrease in products gross margin (to 46.6% in 1994 from 47.0%). The products gross margin decrease was a result of higher costs associated with pilot manufacturing of Accurun(tm). Services gross profit increased 6.1%, or \$76,000, to \$1,326,000 in 1994 from \$1,250,000 in 1993 as the sales decrease was more than offset by an increase in services gross margin (to 28.0% in 1994 from 24.0%). Services gross margin increased primarily as a result of improved economies of scale at its specialty clinical laboratory afforded by higher test volume, and redeployment of staff into Company sponsored research and development projects.

Research and development expenditures increased by 68.3%, or \$190,000, to \$469,000 in 1994 from \$279,000 in 1993 as the Company commenced several research and development projects, including development of Quality Control Panels for molecular diagnostics, increased expenditures related to the development of a PCR test for Lyme Disease, and a second generation Lyme Disease western blot test kit for internal use by the Company's specialty clinical laboratory.

Selling and marketing expenses increased 33.3%, or \$297,000, to \$1,192,000 in 1994 from \$894,000 in 1993. This increase was primarily attributable to staff additions in sales and customer service support for the products business and also higher travel costs.

General and administrative expenses increased 26.4%, or \$428,000, to \$2,047,000 in 1994 from \$1,619,000 in 1993. This increase was primarily attributable to a full year impact of staff additions in information systems, regulatory affairs and accounting in support of the Company's sales growth and growth expectations in both the Quality Control Products and the Specialty Clinical Laboratory Services business.

Interest expense increased 36.4%, or \$65,000, to \$244,000 in 1994 from \$179,000 in 1993 as the Company funded its increased equipment and working capital needs primarily from borrowings.

# LIQUIDITY AND CAPITAL RESOURCES

The Company has financed its operations to date through cash flow from operations, borrowings from banks and sales of equity.

At June 30, 1996 the Company had \$1,398,000 outstanding and \$2,028,000 of availability under its \$3.5 million Revolving Line of Credit Agreement due June 30, 1998 (the "Revolver"). The Revolver bears interest at a rate equal to the prime rate plus 0.5% per annum, currently 8.75%. Prior to June 30, 1996, the Revolver bore interest at a rate equal to the prime rate plus 1% per annum. Under the terms of the Revolver, the Company operates under a zero balance account arrangement whereby cash

receipts are received into a lockbox at the bank and reduce the Revolver, while disbursements for payroll and accounts payable items increase the outstanding balance of the Revolver. Borrowings under the Revolver are limited to 80% of eligible accounts receivable plus the lesser of 40% of inventory or \$1.5 million. The Revolver contains various covenants and restrictions and the amounts outstanding are secured by all of the Company's assets and a \$2 million life insurance policy on an officer/stockholder. See Note 6 to Notes to the Consolidated Financial Statements. The Company expects to use a portion of the proceeds of the Offering to repay the outstanding amount under the Revolver, which at October 4, 1996 was approximately \$2,300,000. See "Use of Proceeds." Amounts repaid on the Revolver will be available for reborrowing.

Net cash provided by operations for the six months ended June 30, 1996 was \$685,000 as compared to \$105,000 in the prior year period. This increase in cash flow was primarily attributable to an increase in net income and an increase in deferred revenue from a payment of \$308,000 under a research contract for future clinical trial services. Cash flow used in operations in 1995, 1994 and 1993 amounted to \$29,000, \$554,000 and \$427,000, respectively. The decrease in cash used in operations in 1995 from 1994 was primarily attributable to an increase in deferred revenue.

Cash used in investing activities for the six months ended June 30, 1996 was \$283,000 as compared to \$216,000 in the prior year period. This increase in investing activities was the result of increased capital expenditures for production equipment associated with Accurun(tm) and other Quality Control Products. Cash used in investing activities for 1995, 1994 and 1993 amounted to \$1,320,000, \$405,000 and \$850,000, respectively. The increased use of cash in 1995 versus 1994 was the result of the purchase of the Company's West Bridgewater facility and in 1993 related to the acquisition of the net assets of North American Laboratory Group Limited, Inc.

Cash used in financing activities for the six months ended June 30, 1996 was \$403,000 as compared to \$151,000 provided by financing activities in the prior comparable year period. Net cash was used in financing activities primarily as a result of the repayment of \$1,591,000 of the Revolver offset by \$899,000 raised through the sale of 117,647 shares of Common Stock to Kyowa Medex, Co., Ltd. in April 1996. Cash provided by borrowings for 1995, 1994 and 1993 amounted to \$1,240,000, \$846,000 and \$494,000, respectively, and net proceeds from the sale of Common Stock for the same periods amounted to \$176,000, \$170,000, and \$765,000, respectively. The proceeds of such debt were used for working capital, to acquire the West Bridgewater property and to purchase capital equipment. The Company expects to use a portion of the proceeds of the Offering to repay the outstanding balances on these notes payable, which aggregated approximately \$1,714,203 at October 23, 1996. See "Use of Proceeds."

Capital expenditures relate primarily to the Company's facilities and related equipment. For the six months ended June 30, 1996 and 1995, capital expenditures totaled \$283,000 and \$216,000 respectively. This represents an increase of \$67,000 in the six months ended June 30, 1996, as the Company continues to invest in manufacturing equipment and information systems related to both operations and finance. In 1995, 1994 and 1993 capital expenditures amounted to \$1,316,000, \$405,000 and \$461,000, respectively. In 1995, \$806,000 of the Company's capital expenditures related to the purchase of the West Bridgewater facility. As of October 4, 1996, the Company has available to it a \$250,000 five year term facility to finance equipment purchases, bearing interest at prime plus 1%.

The Company anticipates capital expenditures to increase over the near term as it expects to use approximately \$1.0 million from the proceeds of this Offering to expand its manufacturing capacity in West Bridgewater over the next 12 months, of which approximately \$500,000 will be spent on building expansion and approximately \$500,000 will be spent on equipment. The Company also expects to use \$522,500 to fund the Company's purchase of its second installment of capital stock of BioSeq following the completion of this Offering. See "Use of Proceeds." The Company must make the remaining \$750,000 installment if BioSeq

attains certain technical milestones by July 31, 1997. If the milestones are not achieved, the Company will have the option to purchase the additional \$750,000 of BioSeq capital stock until December 31, 1997. The Company believes that existing cash balances, the borrowing capacity available under the Revolver, cash generated from operations and the proceeds of this Offering are sufficient to fund operations and anticipated capital expenditures for the foreseeable future. There were no material financial commitments for capital expenditures as of June 30, 1996, and currently there are no material commitments for capital or investment expenditures other than the BioSeq investment.

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On April 26, 1996 the Company entered into a new five year distribution agreement with Kyowa Medex, Co., Ltd., a foreign distributor, extending a six year old relationship. Simultaneously, Kyowa Medex, Co., Ltd. purchased 117,647 shares of the Company's Common Stock at a price of \$8.50 per share. The Purchase Agreement includes a redemption right that may require the Company to repurchase the stock at \$8.50 per share in the event the Company terminates the distribution agreement or it expires prior to the Company completing an initial public offering of its Common Stock. These shares have been presented in the Company's balance sheet separately as redeemable Common Stock. Completion of this initial public offering will terminate the redemption provisions and cause the reclassification of these shares into stockholders' equity.

### RECENT ACCOUNTING PRONOUNCEMENTS

In March 1995, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of" ("SFAS 121"). SFAS 121 requires that an impairment loss be recognized for long-lived assets and certain identified intangibles when the carrying amount of these assets may not be recoverable. The Company has adopted SFAS 121 effective in 1996 and the adoption did not have a material impact on the financial statements.

In October 1995, the FASB issued Statement of Financial Accounting Standards No. 123 ("SFAS 123") "Accounting for Stock-Based Compensation," which becomes effective for fiscal years beginning after December 15, 1995. SFAS 123 establishes new financial accounting and reporting standards for stock-based compensation plans. However, entities are allowed to elect whether to measure compensation expense for stock-based compensation under SFAS 123 or APB No. 25, "Accounting for Stock Issued to Employees." The Company has elected to continue to account under APB No. 25 and will make the required pro forma disclosures of net income and earnings per share as if the provisions of SFAS 123 had been applied in its December 31, 1996 financial statements. The potential impact of adopting this standard on the Company's pro forma disclosures of net income and earnings per share has not been quantified at this time.

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### **BUSINESS**

# **GENERAL**

The Company is a leading worldwide provider of proprietary quality control products for use with in vitro diagnostic test kits ("test kits") for the detection, analysis and monitoring of infectious diseases, including AIDS, Hepatitis and Lyme Disease. These products are used to develop test kits, to permit the monitoring of laboratory equipment and personnel, and to help ensure the accuracy of test results. The Company's products are derived from human plasma and serum using proprietary manufacturing processes. The Company believes its Quality Control Panel products are viewed as the current industry standard for the independent assessment of the performance of HIV and Hepatitis test

kits. The Company also manufactures diagnostic test kit components and provides specialty laboratory services, including clinical trials. The Company's customers include test kit manufacturers, regulatory agencies and end-users of test kits such as blood banks, hospital laboratories and clinical reference laboratories. Currently the Company's products are used in connection with the detection of more than 15 infectious diseases, and its specialty laboratory services are used in connection with the detection of over 100 such diseases.

### INDUSTRY OVERVIEW

According to the World Health Organization ("WHO"), infectious diseases are now the leading cause of premature death around the world and the third most common cause of premature death in the United States. In 1995, more than 17 million people died from exposure to infectious diseases, constituting nearly one-third of the approximately 52 million people worldwide who died from all causes. Currently, the Company focuses on two infectious diseases, Viral Hepatitis and AIDS, which are among the largest killers and are also a primary focus of blood testing efforts worldwide.

WHO estimates that approximately 20 million people worldwide are infected with HIV, and that approximately one million people died from AIDS-related illnesses during 1995. WHO also estimates that up to 350 million people worldwide are infected with Hepatitis Type B, one of several types of Viral Hepatitis, and that over one million people died of Viral Hepatitis during 1995. In developed countries, blood products are routinely screened for HIV and Viral Hepatitis by use of infectious disease test kits.

The increased threat from infectious diseases has created a large and growing market for test kits. Venture Planning Group, a medical products research firm, estimates that the worldwide infectious disease test kit market was approximately \$2.7 billion in 1995, and will grow to \$5.0 billion by 2000 and \$8.0 billion by 2005.

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 include the disposable diagnostic components, instructions, and reaction mixing vessels (generally 96-well plates or test tubes) which are coated with the relevant infectious disease antigens, antibodies or other materials. To perform the test, either a technician or a specially designed instrument typically 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 and radioactive count) which 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) which are specific to a particular pathogen.

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

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 segments: (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.

According to the Genesis Report Dx (May 1994), a medical products survey, the quality control market for in vitro diagnostic testing for infectious and non-infectious disease in 1994 totaled approximately \$600 million. The Company believes that the market for quality control products for infectious disease testing currently represents less than five percent of the overall quality control market. At the present time, most quality control products for non-infectious disease test kits are sold to end-users, who have used quality control products as part of standard laboratory practice for several decades. Conversely, most quality control products for the infectious disease test kit segment of the market are sold to test kit manufacturers and regulators, and not to end-users, who have historically used quality control products only on a limited basis. The Company believes that this lower level of usage among end-users of infectious disease test kits is primarily due to laboratory practices that have evolved from earlier testing methods that did not require routine and extensive use of external quality controls as part of standard laboratory practice. However, the Company also believes that this lower level of usage among end-users of test kits represents a major market opportunity since current testing methods have been improving test kit performance to increasingly higher levels of sensitivity, specificity and reproducibility. The Company believes that these three key criteria of test kit performance can be best monitored through the use of quality control products, such as those sold by the Company.

## MARKET TRENDS

The Company believes that end-users of test kits will become the most significant users of quality control products in the infectious disease market and that the market for infectious disease test kits and related quality control products will continue to expand, primarily as a result of the following four trends.

Increased Regulatory Scrutiny. Due to the high level of public concern with the dangers of infectious diseases, particularly AIDS, Viral Hepatitis, and Lyme Disease, governmental regulatory agencies are requiring additional tests to improve the safety of the blood supply, and are requiring manufacturers and end-users of test kits to adopt quality assurance programs applicable to the entire test kit product life-cycle, from initial product design and development through manufacture and end-use. The passage of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and its regulatory implementation beginning in 1992 have resulted in a set of recommended laboratory practices, including more stringent quality control programs, as well as regular government inspections aimed at improving the overall standard of proficiency in clinical laboratories. As a result, the Company believes that blood bank, hospital and clinical laboratory personnel are adopting more comprehensive quality assurance programs, especially in infectious disease testing, to minimize the risk of errors and to comply with CLIA and other regulations.

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Growing Recognition of the Value of Using Quality Control Products. To ensure the greatest possible safety of the blood supply, to achieve the earliest possible diagnosis of infection, and to minimize the occurrence of false negative results, sensitivity of tests (i.e., their ability to accurately detect very small amounts of the disease marker) is a critical element. The Company

believes there is increasing recognition of the benefit of continuously monitoring test sensitivity using quality control products to help ensure the accuracy of each test run.

New Diseases and the Development of New Therapies. In recent years, HIV, Hepatitis C Virus ("HCV"), Borrelia burgdorferi ("Lyme Disease") and Ehrlichia, among others, have emerged as significant human pathogens. New and drug resistant strains of known pathogens, such as those causing tuberculosis, escape mutants of Hepatitis B Virus ("HBV"), and Group O and other variants of HIV, have also emerged. In response, new and improved tests are being developed. In addition, as new drug therapies are introduced to treat infectious diseases, new tests are needed to monitor the effectiveness of these therapies. For example, the recent advances in AIDS drug therapy, which use a combination of several drugs to treat infected patients, have prompted the creation of a new viral load test used to periodically measure the precise amount of virus in the patient's blood to evaluate the effectiveness of the drug therapy. The Company believes that viral load testing will be applied to additional areas of infectious disease, including Hepatitis B and C and Lyme Disease.

Advanced Test Technologies and Equipment. Test kit manufacturers are continuing to enhance the sensitivity, specificity and reproducibility of their tests. Molecular diagnostics now permit the direct detection of the nucleic acids (DNA and RNA) specific to viruses and other pathogens and are being used to complement traditional microbiological and immunological tests for infectious disease. New tests for urine and saliva have been developed that offer advantages in some settings over blood tests and may be more widely used in the future. Test kit manufacturers are also developing assays on silicon chips, laser-read microspot arrays, and are using electrochemi-luminescence detection, among other technologies. The different types of information obtained through the complementary use of various diagnostic methods can provide the physician with a broader perspective on the diagnosis and prognosis of the disease, as well as on the effectiveness of drug therapy.

### THE BOSTON BIOMEDICA ADVANTAGE

The Company offers a broad, integrated range of products for quality assurance throughout the entire infectious disease 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. To directly address the emerging end-user market opportunity, the Company introduced its TQS marketing platform based around its Accurun(tm) Run Control products. The Company believes that TQS is the first comprehensive package of quality control products designed specifically for infectious disease test kit end-users, providing them with a customized approach to evaluate all of the key elements of the testing process.

The Company believes that it has several competitive advantages which have enabled it to achieve its current leadership position in quality control products for infectious diseases:

Valuable Inventory. The Company has an inventory of approximately 50,000 distinct human blood specimens accumulated since 1986 through its worldwide sources of blood-supply. This inventory cannot be easily or rapidly acquired on the open market, and enables the Company to respond quickly to market trends and customer needs.

Specialty Laboratory Services and Clinical Trials. The knowledge gained through the Company's specialty laboratory services allows the Company to remain at the forefront of emerging market trends and customer needs. By conducting clinical trials of new test kits under development, the Company is able to maintain close contact with manufacturers and to release Quality Control Products for test kits soon after the test kits are introduced to the market. In addition, by operating a specialty clinical laboratory, the Company is able to better understand the requirements of the end-user.

kits and with regulators to help in the evaluation of test kits, the Company has developed proprietary know-how in manufacturing its Quality Control Products.

Reputation. The Company believes that it has developed a reputation as an authority in quality control products for infectious disease among manufacturers and regulators of infectious disease test kits. The Company believes that its reputation, established over the past ten years, will assist it in penetrating the emerging end-user market.

### **STRATEGY**

The Company's strategy is to enhance its leadership position in the infectious diseases quality control market and to take advantage of the emerging opportunities in the end-user market for quality control products. There are five key elements to this strategy:

Capitalize on Emerging End-User Market. In 1996 the Company introduced an expanded line of Quality Control Products that are specifically designed for the end-users of test kits, such as blood banks, hospitals and clinical laboratories. The Company plans to continue to expand its line of Quality Control Products, particularly its Accurun(tm) line of Run Controls, to cover a wider range of immunological and molecular markers. The Company also recently introduced its Total Quality System ("TQS") marketing platform, which combines Accurun(tm) with other Quality Control Products to provide test kit end-users with the products needed in an overall quality assurance program. The Company intends to continue to expand its sales, marketing and distribution activities to support its product development program for the emerging end-user quality control market.

Develop New Products and Services. The Company intends to capitalize on its reputation with manufacturers and regulators by developing Quality Control Products and Diagnostic Components for use with test kits for both new test methodologies and new diseases. For example, in response to a 1996 FDA mandate that all blood collected for transfusion must be tested for the presence of the HIV antigen, the Company recently introduced on an OEM basis the first quality control training panels for use with the two FDA-licensed HIV antigen test kits available in the United States. In addition, the Company has also provided a training panel for end-users of the only FDA-licensed molecular amplification test for HIV RNA, and has introduced a new line of HIV RNA controls to meet the demand of the newly emerging viral load test market. In the future, the Company expects to provide Quality Control Panels for use with tests that distinguish among the subtypes of HIV, the serotypes of HCV, and the various strains of Mycobacteria causing tuberculosis.

Enhance Technical Leadership. The Company seeks to expand its technical capabilities by continually enhancing its strong scientific staff and collaborating with other scientists worldwide, thus strengthening its reputation in the area of quality control for infectious disease testing. The Company maintains and enhances its technical leadership by participating in scientific studies relevant to its products and services, and by making presentations at scientific meetings on blood banking and infectious diseases. The Company's scientists also publish articles in peer reviewed journals.

Capitalize on Complementary Business Operations. The Company intends to capitalize on operational and marketing opportunities that arise out of its activities in both infectious disease products and laboratory services. For example, the Company conducts clinical trials for manufacturers of in vitro diagnostic products, which allows the Company to maintain close contact with test kit manufacturers and regulators, and enables the Company to evaluate new technologies in various stages of development. The Company believes that the reputation and experience of its laboratory and scientific staff, its large number of unique Quality Control Panels, and its inventory of characterized serum and plasma specimens assist the Company in marketing its clinical trial services to its customers. Finally, the Company's specialty clinical laboratory also affords the Company access to materials needed in the production of its Quality Control Products and Diagnostic Components.

strategic acquisitions and alliances to expand its core product lines, to strengthen its base in medical science and technology, and to secure sources of blood supply. To date, the Company has acquired BTRL, a research and development laboratory with a strong capability in molecular and cellular biology, and BBI-NACL, formerly North American Laboratory Group Ltd., Inc., a microbiology and immunology clinical laboratory specializing in the diagnosis of infectious diseases, including tick-borne diseases. These acquisitions led to the introduction in 1994 of the Company's first Quality Control Products for molecular diagnostics. In October 1996, the Company entered into a strategic alliance with BioSeq. Under the License Agreement, upon the earlier of payment of the final installment of the Company's aggregate \$1,482,500 investment and December 31, 1997, the Company will be granted the worldwide right to use technology which is being developed for DNA sequencing and analysis, a process which may allow for more precise identification of infectious disease agents. The Company believes that there may be additional acquisition and alliance opportunities, such as blood donor centers in strategic locations and companies with complementary technology or synergistic product lines, that would strengthen its existing business.

### **PRODUCTS**

The Company designs, develops and markets diagnostic products used for the quality control, quality assurance and technical evaluation of test kits for the laboratory diagnosis of infectious disease. The Company offers three product groups: Quality Control Panels, Run Controls and Diagnostic Components.

The Company manufactures its products from human plasma and serum which are obtained from nonprofit and commercial blood centers, primarily in the United States. The Company has acquired and developed an inventory of approximately 50,000 individual blood units and specimens (with volumes ranging from 1 ml to 800 ml) which provides most of the raw material for its products.

### 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 Products are designed for measuring overall test kit performance and laboratory proficiency, as well as for training laboratory professionals. The Company's Data Sheets are an integral part of its Quality Control Products. 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 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 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 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 and OEM panels range from \$100 to \$200 per panel. The following table describes the types of Quality Control Panel products currently offered by the Company.

```
<TABLE>
<CAPTION>
  PRODUCT LINE
                                                                   CUSTOMERS
                           DESCRIPTION
                                                    USE
 <S>
                                                 <C>
                 <C>
Seroconversion
                                                            Test kit
                     Plasma samples
                                          Compare the
 Panels
                 collected from a
                                     clinical
                                                    manufacturers and
               single individual
                                  sensitivity of
                                                   regulators
              over a specific
                                 competing
              time period showing manufacturers' test
                                   kits, enabling the
               conversion from
              negative to
                                user to assess the
               positive for
                                sensitivity of a
              markers of an
                                  test in detecting a
               infectious disease developing
                            antigen/antibody
Performance
                    A set of 10 to 50
                                       Determine test kit Test kit
 Panels
                 serum and plasma
                                      performance against manufacturers and
               samples collected
                                   all expected levels regulators
               from many different of reactivities in
               individuals and
                                  the evaluation of
               characterized for
                                  new, modified and
               the presence or
                                  improved test
              absence of a
                                 methods
              particular disease
              marker
Sensitivity Panels
                    Precise dilutions
                                                          Test kit
                                        Evaluate the
               of human plasma or
                                   low-end analytical manufacturers
               serum containing a
                                    sensitivity of a
              known amount of an test kit
              infectious disease
              marker as
               calibrated against
               international
               standards
                                                             Clinical reference
Qualification
                   Dilutions of human Demonstrate the
 Panels
                 plasma or serum
                                     consistent
                                                      laboratories, blood
               manifesting a full
                                  lot-to-lot
                                                  banks, and hospital
               range of
                               performance of test laboratories
              reactivities in
                                kits, troubleshoot
              test kits for a
                                problems, evaluate
               specific marker
                                  proficiency, and
                            train laboratory
                            technicians
                                                             Custom designed
OEM Panels
                     Custom-designed
                                          Train laboratory
               Qualification
                                                     with test kit
                                 personnel on new
```

Panels for test kits or manufacturers and regulators and test equipment kit manufacturers
for distribution to for internal use

customers or for internal use

</TABLE>

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 equally unique and rare. The Company believes that its inventory and relationships with blood centers affords it a competitive advantage in acquiring such plasma for replacement panels and developing new products to meet market demand. There can be no assurance that the Company will be able to continue to obtain such specimens. See "Risk Factors -- Difficulty in Obtaining Raw Materials."

The Company believes that it offers its customers a broad range of Quality Control Panel products to address the requirements of the complete life-cycle of a test kit, from initial research and development, through the regulatory approval process, test kit production, training, troubleshooting and routine use by end-users. The Company further believes that its Data Sheets, an integral part of all panel products, offer its customers in-depth information on a particular test kit of interest. Quality

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Control Panels currently span the immunologic markers for AIDS (i.e., HIV), Hepatitis B and C, Lyme Disease and ToRCH (Toxoplasma, rubella, cytomegalovirus and herpes simplex virus). New introductions this year include molecular Performance Panels for HBV and HCV, qualification panels for HIV, HBV and HCV, and additional Seroconversion Panels for HIV, HBV, and HCV.

# ACCURUN(TM) RUN CONTROLS

End-users of test kits utilize Run Controls to confirm the validity of results by monitoring test performance, thereby minimizing false negative test results and improving error detection. Run controls consist of one or more specimens of known reactivity that are tested together 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, determined by the user, to measure whether the other 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 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 believes its Accurun(tm) product line provides the following benefits to end-users:

- \* Helps to satisfy the requirements of Good Laboratory Practice.
- \* Tracks the accuracy and precision of test runs.
- \* Detects laboratory errors and identifies trends before they become a problem.
- \* Monitors test kit performance, equipment and personnel.
- \* Helps to meet National Committee For Clinical Laboratory Standards ("NCCLS") for molecular and immunological diagnostic methods for infectious disease quality control.
- \* Documents the validity of test results, day to day, week to week.

The Company introduced its first four Accurun(tm) Run Control products in the fourth quarter of 1993 and has since developed and released for sale an additional 24 Accurun(tm) products. A limited number of these products are available for diagnostic purposes; the others currently are limited to research use. See " -- Government Regulation." Current Accurun(tm) Run Control products range in price from \$15 to \$45 per milliliter and are described in the following table.

immunological tests Accurun(tm) 100-199 Single-marker Run Control 17 Hospitals and clinical for immunological tests reference laboratories Accurun(tm) 200-299 Multi-marker Run Control for Research and specialty - 1 molecular tests laboratories Accurun(tm) 300-399 Single-marker Run Control Research and specialty for molecular tests laboratories Accurun(tm) 800-899 Negative Run Control for 3 All laboratories immunological and molecular tests </TABLE>

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The Company's Accurun(tm) 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(tm) products, in combination with its Quality Control Panel products, provide an extensive line of products for quality assurance in infectious disease testing. See "-- Sales and Marketing." The Company intends to continue to expand its line of Accurun(tm) products, thereby providing its customers with the convenience and cost effectiveness of a single supplier for independent run controls. See "Risk Factors -- Undeveloped End-User Market For Quality Control Products for Infectious Disease Test Kits."

The Company has received 510(k) clearance from the FDA to market its Accurun 1(R) line, for diagnostic purposes, and intends to apply for such clearance for the remainder of its Accurun(tm) products. All of the Company's Accurun Run Controls will require FDA premarket clearance or approval prior to being marketed for diagnostic use. An application for clearance for diagnostic use for one additional Accurun(tm) product has been submitted by the Company to the FDA, and the Company anticipates that applications for approximately 16 additional Accurun(tm) products will be prepared and submitted to the FDA by the end of 1997. Failure to obtain, or delays in obtaining, such clearance or approval would adversely affect the Company's strategy of capitalizing on the end-user market. See "Risk Factors -- Stringent Government Regulation" and "-- Government Regulation."

# DIAGNOSTIC COMPONENTS

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

The Company believes that it has several competitive advantages in Diagnostic Components. Through its trained and experienced laboratory staff, the Company is able to perform comprehensive in-house testing for a number of markers in a particular material, and consequently is able to address the demands of its customers. The Company's large inventory of approximately 50,000 specimens provides it with the flexibility to produce Diagnostic Components efficiently and rapidly in response to customer requests. The Company believes that its proprietary manufacturing knowledge enables it to manufacture stable, high quality products to meet the demands of its worldwide customer base.

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

Specialty Clinical Laboratory Testing. The Company operates an independent specialty clinical laboratory which performs both routine and sophisticated infectious disease testing in microbiology, immunology and molecular biology, with special emphasis in AIDS, Viral Hepatitis and Lyme Disease. The Company's specialty clinical laboratory combines traditional microbiology, advanced immunology, and current molecular diagnostic techniques, such as PCR, to detect and identify microorganisms, their antigens and related antibodies, and their nucleic acids (i.e., DNA and RNA). Customers include physicians, clinics, hospitals and other clinical/research laboratories.

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Contract Research. The Company offers a variety of contract research services in molecular biology, cell biology and immunology to governmental agencies, diagnostic test kit manufacturers and biomedical researchers. Molecular biology services include DNA sequencing, recombinant DNA support, probe labeling and custom PCR 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 or nucleic acids, and production of antibodies. The Company is currently providing research services for assessment of the efficiency of candidate HIV vaccines in a monkey model system under two separate contracts with the National Institute for Allergy and Infectious Disease ("NIAID"), a part of the National Institutes of Health ("NIH"). Each of these contracts has a two year term which expires in September 1997. In addition, since 1983, the Company, through its BTRL subsidiary, has provided blood processing and repository services for the National Cancer Institute ("NCI"), also a part of the NIH. The repository stores over 2,000,000 specimens and processes or ships up to several thousand specimens per week in support of various NIH cancer and virus research programs. While the current NCI repository contract terminates in February 1997, the Company has responded to a Request for Proposals by the United States government for a new four year contract to replace this contract. There can be no assurance that any of these contracts will be replaced with new contracts. See "Risk Factors --Dependence on Key Customers."

Small Business Innovation Research ("SBIR") grants and other government contracts similar to the ones described have enabled the Company to develop technologies applicable to new product development and its specialty clinical laboratory. For example, recent SBIR grants have enabled the Company to develop PCR based assays for the detection of the nucleic acids of HIV, HCV and Lyme Disease. Although the Company does not currently have any SBIR grants, it has two pending applications for such grants and intends to continue to seek government grants and contracts that further the Company's core technology and commercial business. There can be no assurance that the Company will receive any government research grants in the future.

Clinical Trials. The Company conducts clinical trials for domestic and foreign test kit manufacturers. Test kit manufacturers must conduct such trials to collect data for submission to the United States FDA and other regulatory agencies. By providing this service, the Company is able to maintain close contact with test kit 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 manufacturers seeking to obtain FDA approval for their infectious disease test kits.

Drug Screening Program. As a subcontractor for an NIH AIDS grant held by the University of North Carolina at Chapel Hill, the Company has established an anti-HIV drug screening program to test a large number of natural products

(largely plant derivatives) to determine whether they inhibit HIV replication in an in vitro assay system. These in vitro assays are also offered as a service to researchers and pharmaceutical companies who wish to test various candidate anti-viral agents for anti-HIV activity.

### RESEARCH AND DEVELOPMENT

The Company's research and development effort is focused on the development of (i) new and improved Quality Control Products for the emerging end-user market, (ii) new products for existing customers, (iii) Diagnostic Components for use with test kits for both new test methodologies and new diseases, and (iv) infectious disease testing services using PCR and other amplification assays for AIDS, Viral Hepatitis, Lyme Disease and Chlamydia, among others. The Company has approximately 20 full or part-time employees dedicated to its research and development effort. For the six months ended June 30, 1996 the Company increased spending on research and development as a percentage of revenues compared to the same period ended June 30, 1995 and expects to continue to increase such expenditures as a percentage of revenues for the next several years. 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 and manufacturing personnel to identify and prioritize the development of new products and services.

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The Company's product development activities center on the identification and characterization of materials for the manufacture of new Quality Control Products and the replacement of sold-out products. For example, during 1996, the Company has introduced 10 new Seroconversion, Performance and Sensitivity Panel products as well as 14 new Accurun(tm) Run Controls; in addition, during July 1996, the Company released its first Qualification Panel products. The Company is developing new Quality Control Products for use with molecular diagnostic tests for HIV, HCV and HBV. Recently the Company expanded its Quality Control Product line beyond the retrovirus and Viral Hepatitis diagnostics area to include sexually transmitted diseases (e.g., Syphilis), tick-borne diseases (e.g., Lyme Disease), and respiratory and other infections (e.g., Tuberculosis) and is continuing to develop new Quality Control Products for these and other diseases. The Company has increased the number of Quality Control Products it offers from approximately 20 in 1990 to approximately 150 products in 1996.

The Company is also developing new and improved infectious disease specialty tests for Lyme Disease and other tick-borne diseases for use in its specialty laboratory business. For example, the Company was among the first to develop enzyme immunoassays and Western Blot assays for Lyme Disease. The Company is also pursuing new applications of PCR technology to infectious disease diagnostics, such as amplification assays for the pathogens of AIDS, Viral Hepatitis, Lyme Disease and Chlamydia, and for the direct detection of other infectious agents in blood, tissues and other body fluids.

From time to time in the past, the Company has funded a portion of its research and development activities from grants provided by various agencies and departments of the U.S. government. See "-- Services."

## STRATEGIC ALLIANCES

University of North Carolina at Chapel Hill. The Company is directly supporting a drug discovery program at UNC, in which a full-time research scientist is working to develop synthetic derivatives of anti-HIV compounds that have been discovered pursuant to the Company's joint collaboration with UNC. This research scientist is also working to introduce modifications to these derivatives that would make them more soluble, less toxic, or otherwise enhance their anti-viral properties. UNC has licensed to the Company exclusive worldwide rights to three series of patent applications filed by the Company and UNC with respect to three classes of anti-HIV compounds. Two such compounds have exhibited therapeutic indices in in vitro test model systems in excess of those recorded for AZT under comparable test conditions. The Company is expending approximately \$100,000 per year for research and development relating to these compounds. In addition, under this license, the Company will also have the rights to any new anti-HIV compounds or derivatives developed in the course of this sponsored research, provided the Company obtains certain regulatory

Ajinomoto Co., Inc. The Company entered into an agreement with Ajinomoto Co., Inc. in October 1995 pursuant to which the Company is performing research regarding among other things, whether tests for certain amino acids in plasma can be used to determine a person's immune status, particularly in chronic fatigue syndrome. This project is funded by Ajinomoto and has a three year budget of approximately \$1,000,000. Discoveries and inventions arising from the research will be owned by Ajinomoto, but the Company has the right of first refusal to obtain certain exclusive licenses from Ajinomoto of any patented technology arising from the research. The Company is entitled to certain royalties based upon a percentage of sales of products arising out of the research. This agreement expires in September 1998.

BioSeq, Inc. In October 1996, the Company entered into a strategic alliance with BioSeq, an early stage biotechnology company that is developing a technology that may, through the use of pressure, be able to more precisely control chemical reactions. The Company believes that this technology may be useful for sequencing, synthesizing and characterizing nucleic acids and proteins, which may then allow for the more precise identification of infectious disease agents.

The Company has agreed to purchase approximately 19% of the capital stock of BioSeq for an aggregate of \$1,482,500 in three installments. Of the \$1,482,500, \$210,000 has been invested and \$522,500 will be invested upon completion of the Offering. The Company must make the remaining \$750,000 installment if BioSeq attains certain technical milestones by July 31, 1997. If such milestones are not attained by BioSeq by July 31, 1997, the Company will have the option to make the remaining \$750,000 investment until December 31, 1997. See "Use of Proceeds." The Company has price anti-dilution protection, pre-emptive rights and the right to board representation, the last of which terminates if the Company fails to make the second installment

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under the Purchase Agreement. In addition, the Company was granted the right to acquire additional shares of common stock of BioSeq for additional consideration under certain conditions, provided that this right is not exercisable to the extent it would cause the Company's ownership of BioSeq to equal or exceed 20%. BioSeq has also agreed to engage the Company to perform a minimum of \$100,000 and \$150,000 of research and development services following the payment of the second and third installments, respectively.

Under the License Agreement, upon the earlier of payment of the final installment of the Company's investment and December 31, 1997, the Company will be granted a worldwide right to use the BioSeq technology relating to sequencing and analysis services. The License will be exclusive until BioSeq commences selling on a commercial basis the equipment used in the DNA sequencing and analysis process, at which time the License will become non-exclusive. The License provides that the Company will pay BioSeq certain royalties based upon net revenues arising out of the services performed by the Company with the licensed technology.

## SALES AND MARKETING

The Company's sales and marketing efforts are directed by a Senior Vice President of Sales and Marketing who supervises 15 sales people and four other full-time sales and marketing employees.

The Company's marketing strategy is focused upon addressing the needs of its customers in the infectious disease testing market throughout the entire test kit life-cycle, from initial research and development, through the regulatory approval process and test kit production, to training, troubleshooting and routine use by end-users such as clinical laboratories, hospitals and blood banks. By serving its customers at all stages of the product life-cycle, the Company expects to stay at the forefront of trends in infectious disease testing, which in turn enables the Company to anticipate and respond to the needs of the marketplace.

The Company recently has begun to focus its sales and marketing efforts on the emerging end-user market for quality control products for infectious disease test kits. To promote this objective, the Company is implementing a major marketing platform, known as "Total Quality System" ("TQS"). TQS is a package of Quality Control Products, including the Company's Accurun(tm) Run Controls, which is designed to provide test kit end-users with the products needed in an overall quality assurance program. These products enable laboratories to evaluate each of the key elements involved in the testing process: the test kit, laboratory equipment and laboratory personnel. The Company believes that TQS effectively addresses the need for end-users to ensure the accuracy of their test results. The Company intends to continue to expand its sales and marketing activities with respect to its Accurun(tm) line of Run Control products. Since the beginning of 1996, the Company has hired two new employees for the sales and marketing of its Accurun(tm) line of products and expects to add six more direct salespeople by the end of 1997.

The Company's products are currently sold through a combination of telephone, mail, third party distributors and limited direct sales efforts. Domestically, products are sold through an in-house tele-sales group consisting of five sales representatives, two sales managers and one customer service representative. Internationally, the Company distributes its products both directly and through 17 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. During the fiscal years 1993, 1994, 1995 and the six months ended June 30, 1995 and 1996 the Company's distributors accounted for 1.9%, 3.5%, 6.2%, 2.8% and 8.8% of the Company's total revenue, respectively. The Company intends to further expand sales through international distributors, although there can be no assurances that it will be able to do so. See "Risk Factors -- Risks Associated with Export Sales."

The Company's Specialty Clinical Laboratory Testing services are marketed primarily through a direct domestic sales force consisting of seven sales representatives managed by a sales director. The sales representatives are located throughout the eastern and mid-western United States. They are supported internally by a client services representative.

The Company emphasizes high quality products and services, technical knowledge, and responsiveness to customer needs in its marketing activities for both products and services. The Company educates its distributors, customers and prospective customers about its products through a series of detailed marketing brochures, technical bulletins and pamphlets, press releases and direct mail pieces. These materials are supplemented by advertising campaigns in major industry publications, technical presentations, and exhibitions at local, national and international trade shows and expositions.

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# **CUSTOMERS**

The Company's customers for Quality Control Products and Diagnostic Components comprise three major groups: (i) international diagnostics and pharmaceutical manufacturing companies, such as Abbott Diagnostics, Behring, Boehringer Mannheim, Chiron, Fujirebio, Hoffman LaRoche, Ortho Diagnostics (Johnson and Johnson), Sanofi Diagnostics and Sorin Biomedica; (ii) regulatory agencies such as the United States FDA, the British Public Health Laboratory Service, the French Institut National de la Transfusion Sanguine, and the German Paul Ehrlich Institute; and (iii) end-users of diagnostic test kits, such as hospital clinical laboratories, public health laboratories and blood banks, including the Swiss Red Cross, United Blood Services and Kaiser Permanente. In 1995, the Company sold products to approximately 100 diagnostics and pharmaceutical manufacturers, 15 regulatory agencies, and 250 end-users. The Company's Specialty Clinical Laboratory Testing services are sold to hospital and clinical laboratories, blood banks, researchers and other health care providers. The Company's Contract Research services are typically offered under contracts to governmental agencies, diagnostic test kit manufacturers and biomedical researchers. See "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Overview."

The Company does not have long-term contracts with its customers for Quality Control Products and Diagnostic Components. The Company's products are sold to its customers pursuant to purchase orders for discrete purchases. Although the Company believes that its relationships with these customers are satisfactory, termination of the Company's relationship with any one of such customers could have a material adverse effect on the Company. See "Risk Factors -- Dependence on Key Customers."

During the fiscal years 1993, 1994 and 1995, and the six months ended June 30, 1995 and 1996, sales to the Company's three largest customers accounted for an aggregate of approximately 20% of the Company's net sales, although the customers were not identical in each period and no one customer accounted for more than 10% of net sales.

#### MANUFACTURING AND OPERATIONS

The Company manufactures and assembles substantially all of its products at its facility in West Bridgewater, Massachusetts. The Company has computerized purchasing, inventory, and test result and materials tracking systems in an integrated operations management system, and believes that these systems are adequate for its current level of production, but would require further enhancements if the Company experiences substantial future growth. The Company acquires raw materials from a variety of vendors and through a program of donor recruitment, donor screening, product collection, product characterization and donor management. All important materials have multiple sources of supply.

The Company's West Bridgewater facility contains environmentally-controlled freezers and cold rooms, which are used to store raw materials for manufacturing and finished products. More than 3,000 square feet of space in the West Bridgewater facility is dedicated to freezers and cold rooms. The freezers and cold rooms are monitored continuously and the Company maintains a natural gas fired emergency generator in the event of a power outage.

The Company also operates a specialty clinical laboratory in New Britain, Connecticut and a research and development laboratory in Rockville, Maryland. See "-- Properties."

# COMPETITION

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

In the area of Quality Control Products, the Company competes in the United States primarily with NABI (formerly North American Biologicals, Inc.) in Run Controls and Quality Control Panel products and Blackhawk Biosystems Inc. in Run Controls. In Europe, the Netherlands Red Cross has recently

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begun offering several Run Control and panel products. The Company believes that all three of these competitors currently offer a more limited line of products than the Company, although there can be no assurance these companies will not expand their product lines.

In the Diagnostic Components area, the Company competes against 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 Company believes that it has competitive advantages in the quality control products and diagnostic components industry. These include its access to raw materials, technical know-how, broad product line and established reputation among large diagnostics and pharmaceutical manufacturers, as well as regulatory agencies.

In the Specialty Clinical Laboratory Testing services portion of the Company's business, it competes with large national reference laboratories, such as LabCorp of America, Corning Clinical Laboratories and SmithKline Beecham Clinical Laboratories, as well as several independent regional laboratories, hospital laboratories, government contract laboratories and large research institutions. The Company believes that by focusing on the specialty clinical laboratory market, it is able to offer its customers a higher value-added service on the more complex diagnostic tests than the larger national reference laboratories.

### 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. See "Risk Factors -- Stringent Government Regulation."

In the United States, the Food, Drug, and Cosmetic Act ("FDCA") prohibits the marketing of 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 FDA finding the product to be substantially equivalent to a legally 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 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 Run Controls, when marketed for diagnostic use, have been classified by the FDA as medical devices. The Accurun 1(R) Multi-Marker Run Control, which include eight analytes, has been cleared through the 510(k) process. The Company expects that, in the future, most of its products that need FDA premarket review also will be reviewed through the 510(k) process. The FDA could, however, 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. There can be no assurance that the Company 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.

All of the Company's Quality Control Products, with the exception of Accurun 1(R), are marketed "for research use only," which do not require FDA premarket clearance or approval, and not for diagnostic uses, which do require FDA premarket clearance or approval. 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 prior to marketing, and initiate enforcement action against the Company, which could have a material adverse effect on the Company.

Once cleared or approved, medical devices are subject to pervasive and continuing regulation by the FDA, including, but not limited to, good manufacturing practices ("GMP") regulations governing testing, control, and documentation; and reporting of adverse experiences with the use of the device.

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Ongoing compliance with GMP and other applicable regulatory requirements is monitored through periodic inspections. FDA regulations require agency 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. There can be no assurance, 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.

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 the European Union members and the European Free Trade Association members) are in the process of adopting various product and services "Directives" to address essential health, safety, and environmental requirements associated with the subject products and services. The "Directives" cover both quality system requirements (ISO Series 9000 Standards) and product and marketing related requirements. In addition, some jurisdictions have requirements related to marketing of the Company's products. There can be no assurance that the Company 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 (College of American Pathologists), and other national regulatory agencies (Health Care Financing Administration). Studies to evaluate the safety or effectiveness of FDA regulated products (primarily human and animal drugs or biologics) must also be conducted in conformance with relevant FDA requirements, including Good Laboratory Practice ("GLP") regulations, investigational new drug or device regulations, Institutional Review Board ("IRB") regulations and informed consent regulations.

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

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

The Company is also subject to government regulation under the Clean Water Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the Atomic Energy Act, and other national, state and local restrictions relating to the use and disposal of biohazardous, radioactive and other hazardous substances and wastes. The Company is an exempt small quantity generator of hazardous waste

and has a U.S. Environmental Protection Agency identification number. The Company is also registered with the U.S. Nuclear Regulatory Commission for use of certain radioactive materials. All hazardous waste is manifested and disposed of properly. 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.

#### INTELLECTUAL PROPERTY

None of the Company's Quality Control Products or Diagnostic Components have been patented. The Company has decided to hold as trade secrets current technology used to prepare Basematrix and other blood-based products. The Company relies primarily on a combination of trade secrets and non-disclosure and confidentiality agreements, and in certain limited circumstances, patents, to establish and protect its proprietary rights in its technology and products. There can be no assurance that others will not independently develop or otherwise acquire the same, similar or more advanced trade secrets and know-how.

The Company has two United States patents and, jointly with UNC, has filed three series of United States and foreign patent applications relating to compounds, pharmaceutical compositions and therapeutic methods in connection with the Company's drug discovery program at UNC. See "-- Services," and " -- Research and Development."

The Company has no reason to believe that its products and proprietary methods infringe the proprietary rights of any other party. There can be no assurance, however, that other parties will not assert infringement claims in the future. See "Risk Factors -- Protection of Intellectual Property and Proprietary Technology."

## **PROPERTIES**

The Company's corporate offices and manufacturing facilities are located in a two story, 22,500 square foot building in West Bridgewater, Massachusetts. The Company owns and operates this building. The Company intends to use approximately \$1 million of the proceeds of this Offering to expand its manufacturing capacity and to purchase necessary equipment at its West Bridgewater site, and has submitted plans to local authorities for the development of an additional 7,500 square feet, primarily for manufacturing purposes. The Company anticipates that these renovations will begin this year. The Company believes that following these renovations, its facility in West Bridgewater will be sufficient to meet its foreseeable needs. See "Use of Proceeds."

The Company leases its laboratory facilities in Rockville, Maryland and New Britain, Connecticut. The Rockville facility contains 21,000 square feet and is occupied under a five-year lease that is due to expire on June 30, 1997. The Company is currently considering the exercise of its option to extend the lease for an additional five years, as well as relocating its laboratory. The Company believes that there is sufficient space available in the Rockville facility for its current needs. The New Britain facility has 15,000 square feet, most of which is dedicated to laboratory space. The lease is for five years and is due to expire on July 30, 2000; the Company has an option to renew for an additional five years.

# **EMPLOYEES**

As of October 23, 1996 the Company employed 186 persons, all of whom were located in the United States. Seventy-seven of these persons were employed in West Bridgewater, Massachusetts, 59 in New Britain, Connecticut, and 50 at the Rockville, Maryland site. None of the Company's employees is covered by a

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### MANAGEMENT

#### DIRECTORS AND EXECUTIVE OFFICERS

The directors and executive officers of the Company and their ages are as follows:

<table></table>		
<caption></caption>		
NAME	AGE	POSITION
<s></s>	<c> <c></c></c>	•
Richard T. Schumacher(1)	46	
		an of the Board
Kevin W. Quinlan(2)	46	Senior Vice President, Finance; Chief
	Financia	al Officer; Treasurer and Director
Patricia E. Garrett, Ph.D.	53	Senior Vice President, Regulatory Affairs &
	Strategi	c Programs
Mark M. Manak, Ph.D.	45	Senior Vice President, Research and
	Develop	oment
Richard C. Tilton, Ph.D.	60	Senior Vice President, Specialty Laboratory
	Services	S
Barry M. Warren	49	Senior Vice President, Sales & Marketing
•		
Ronald V. DiPaolo, Ph.D.	52	Vice President of Operations
ŕ		•
Francis E. Capitanio(2)	52	Director
•		
Henry A. Malkasian(1)	79	Director
, ,		
Calvin A. Saravis(1)(2)	66	Director

- (1) Member of the Compensation Committee.
- (2) Member of the Audit Committee.

</TABLE>

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

Dr. Garrett has been Senior Vice President, Regulatory Affairs & Strategic Programs since 1988. 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, Research and Development since 1992. From 1980 to 1992, he served as Senior Research Scientist, Molecular

Dr. Tilton has served as Senior Vice President, Specialty Laboratory Services since the Company's acquisition of BBI-North American Clinical Laboratories, Inc. in 1993 and was one of the founders of BBI-NACL, where he served as President from 1989 to 1993. Dr. Tilton has 25 years of experience in university hospital clinical microbiology laboratories and is board certified in medical and public health microbiology. Dr. Tilton received his Ph.D. in microbiology from the University of Massachusetts.

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

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

Mr. Capitanio has served as a Director since January 1986. He has been 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., since 1980. 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.

Mr. Malkasian has served as a Director since the Company's organization in 1978. Mr. Malkasian is a practicing attorney-at-law and a member of the firm Malkasian & Budge in Massachusetts. He received his J.D. degree from Harvard University School of Law and a B.A. degree from Clark University.

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

In August 1990 the Board of Directors established a Compensation Committee currently composed of Messrs. Schumacher, Saravis and Malkasian. The functions of the Compensation Committee include presentation and recommendations to the Board of Directors on compensation levels for officers and directors and issuance of stock options to the Board of Directors, employees and affiliates.

In August 1990 the Board of Directors established an Audit Committee currently composed of Messrs. Capitanio, Quinlan and Saravis. The functions of the Audit Committee include recommending to the Board of Directors the engagement of the independent accountants, reviewing the scope of internal controls and reviewing the implementation by management of recommendations made by the independent accountants.

The Company's Board of Directors is divided into three classes, with the classes being elected for staggered three-year terms. At each annual meeting of stockholders, directors will be elected to succeed those in the class whose term then expires, and each elected director shall serve for a term expiring at the third succeeding annual meeting of stockholders after such director's election, and until the director's successor is elected and qualified. Thus, directors stand for election only once in three years. Executive officers serve at the discretion of the Board of Directors.

### DIRECTOR COMPENSATION

Directors of the Company do not receive cash compensation for their services. Each director is eligible to receive options to purchase Common Stock under the Company's 1987 Non-Qualified Stock Option Plan. As of October 4, 1996, options to purchase an aggregate of 249,750 shares have been granted to directors of the Company under this Plan. During fiscal 1995, options to purchase an aggregate of 15,000 shares of Common Stock were granted to the Directors as follows: 5,000 shares to Mr. Capitanio, 5,000 shares to Mr. Malkasian, and 5,000 shares to Dr. Saravis and no shares to either Mr. Schumacher or Mr. Quinlan.

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### EXECUTIVE COMPENSATION

The following table sets forth the compensation for the fiscal year ended December 31, 1995 of each of the Chief Executive Officer and the six most highly compensated officers of the Company (the "Named Executive Officers"), none of whom received any bonuses during the fiscal year ended December 31, 1995:

### SUMMARY COMPENSATION TABLE

<TABLE> <CAPTION>

# ANNUAL COMPENSATION FOR FISCAL 1995 OTHER ANNUAL

# NAME AND PRINCIPAL POSITION SALARY(\$) COMPENSATION(\$)

<\$> <<	<c></c>	
Richard T. Schumacher	\$166,676	\$ 2,008(1)
President and Chief Executive Officer		
Kevin W. Quinlan	120,615	1,650(2)
Senior Vice President, Finance and Chief Financial Office	er	
Patricia E. Garrett, Ph.D.	92,353	1,650(2)
Senior Vice President, Regulatory Affairs & Strategic Pr	rograms	
Mark M. Manak, Ph.D.	. 102,753	
Senior Vice President, Research & Development		
Richard C. Tilton, Ph.D.	111,924	6,000(3)
Senior Vice President, Specialty Laboratory Services		
Barry M. Warren	113,454	1,500(2)
Senior Vice President, Sales & Marketing		
Ronald V. DiPaolo, Ph.D.	. 86,614	1,500(2)
Vice President of Operations		

(1) Consists of personal usage of Company vehicle, and includes the value of premiums paid for a term life insurance policy.

- (2) Consists of automobile allowance, discontinued as of March 31, 1995.
- (3) Consists of automobile allowance.

</TABLE>

The following table sets forth the aggregate number and value of options exercisable and unexercisable by the Named Executive Officers during fiscal 1995. No stock options were granted to, or exercised by, any of the Named Executive Officers in fiscal 1995.

## FISCAL YEAR-END OPTION VALUES

<TABLE>

<CAPTION>

<s></s>	<c> ·</c>	<c></c>		
Richard T. Schumacher	127,500	2,500	\$ 988,500	\$ 16,250
President and Chief Executive O	fficer			
Kevin W. Quinlan	58,000	10,000 4	103,750	65,000
Senior Vice President, Finance a	nd Chief			
Financial Officer				
Patricia E. Garrett, Ph.D	41,250	1,250 3	34,125	5,625
Senior Vice President, Regulator	ry Affairs &			
Strategic Programs				
Mark M. Manak, Ph.D	26,250	8,750	170,625	56,875
Senior Vice President, Research	& Development			
Richard C. Tilton, Ph.D	17,500	17,500	105,000	105,000
Senior Vice President, Specialty	Laboratory			
Services				
Barry M. Warren	7,500	7,500 33	3,750 33	3,750
Senior Vice President, Sales & M	C			
Ronald V. DiPaolo, Ph.D	25,000	1,000	183,900	4,500
Vice President of Operations				

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#### </TABLE>

(1) There was no public trading market for the Common Stock as of December 31, 1995. Accordingly, these values have been calculated on the basis of the assumed initial public offering price of \$9.00 per share, less the applicable exercise price.

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### **EMPLOYMENT AGREEMENTS**

None of the Company's employees are subject to employment agreements with the Company.

## STOCK PLANS

1987 Non-Qualified Stock Option Plan: The Company adopted the 1987 Non-Qualified Stock Option Plan (the "Non-Qualified Plan") to provide an opportunity to employees, officers, directors and consultants employed by or affiliated with the Company or any of its subsidiaries to acquire stock in the Company, to provide increased incentives to such persons to promote the success of the Company's business and to encourage such persons to become affiliated with the Company through the granting of options to acquire its capital stock. Any employee of the Company or of a subsidiary of the Company, including officers, as well as directors of the Company and consultants or providers of services to the Company, are eligible to receive nonqualified stock options under the Non-Qualified Plan. A total of 897,600 shares of Common Stock has been reserved for issuance under the Non-Qualified Plan.

The Non-Qualified Plan is required to be administered by a Committee consisting of at least one member appointed by the Board of Directors, and after the completion of this Offering, consisting of at least two independent members of the Board of Directors. The Committee currently consists of Richard Schumacher, Kevin Quinlan and Henry Malkasian. The Committee has the authority and discretion to determine those persons to whom options shall be granted under the Non-Qualified Plan, to determine the number of shares to be granted, to establish the terms and conditions upon which options may be exercised or transferred, to alter any restrictions or conditions on the options and to make all other determinations necessary or desirable for the administration of the Non-Qualified Plan. The exercise price for options granted under the Non-Qualified Plan is determined by the Committee, but is in no event less than the par value of the Common Stock. Options granted under the Non-Qualified Plan continue in effect for such period as the Committee determines. The Non-Qualified Plan terminates as of December 16, 1997.

As of October 4, 1996, options to purchase 749,850 had been issued pursuant to the Non-Qualified Plan at exercise prices ranging from \$.25 to \$6.00, including an aggregate of 249,750 shares to the Company's directors, Richard Schumacher, Kevin Quinlan, Francis Capitanio, Henry Malkasian, and Calvin

Employee Stock Option Plan: The purpose of the Employee Stock Option Plan (the "Employee Plan") is to provide increased incentives to employees, to encourage new employees to become affiliated with the Company and to associate more closely the interests of such persons with those of the Company. The Employee Plan permits the issuance of options to purchase up to 750,000 shares of Common Stock in the form of incentive stock options as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and non-qualified stock options. The Employee Plan is currently administered by a Committee consisting of at least one member appointed by the Board of Directors, and after the completion of this Offering, shall consist of at least two independent members of the Board of Directors. The exercise price of stock options is determined by the Committee, but is in no event less than par value, and the exercise price of incentive stock options may not be less than the fair market value of the Common Stock on the date of grant (or, in the case of holders of 10% or more of the outstanding Common Stock, 110% of the fair market value on such date). The Committee also determines the vesting schedule, number of shares and other terms of the options. As of October 4, 1996, options to purchase 184,537 shares of Common Stock at exercise prices ranging from \$6.00 to \$8.50 per share were outstanding under the Employee Plan.

### COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

The Compensation Committee currently consists of Messrs. Schumacher and Malkasian and Dr. Saravis, each of whom has received options to purchase shares of Common Stock. See "-- Director Compensation" and "-- Stock Plans."

# LIMITATION OF OFFICERS' AND DIRECTORS' LIABILITY; INDEMNIFICATION AGREEMENTS

The Company's Amended and Restated Articles of Organization eliminate, subject to certain exceptions, the personal liability of directors to the Company or its stockholders for monetary damages for breaches of fiduciary duties as directors. The Restated Articles do not provide for the elimination of or any limitation on the personal liability of a director for (i) any breach of the director's duty of loyalty

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to the Company or its stockholders, (ii) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) certain unauthorized dividends, redemptions or distributions as provided under Section 61 of the Massachusetts Business Corporation Law, (iv) certain loans of assets of the Company to any of its officers or directors as provided under Section 62 of the Massachusetts Business Corporation Law or (v) any transaction from which the director derived an improper personal benefit. This provision of the Amended and Restated Articles of Organization will limit the remedies available to a stockholder in the event of breaches of any director's duties to such stockholder or the Company.

The Company's Amended and Restated Articles of Organization provide that the Company may, either in its By-laws or by contract, provide for the indemnification of directors, officers, employees and agents, by whomever elected or appointed, to the full extent permitted by law, as it may be amended from time to time.

The Company intends to enter into indemnification agreements with each of the directors and officers. The indemnification agreements will provide that the Company will pay certain amounts incurred by a director or officer in connection with any civil or criminal action or proceeding and specifically including actions by or in the name of the Company (derivative suits) where the individual's involvement is by reason of the fact that he is or was a director or officer. Such amounts include, to the maximum extent permitted by law, attorney's fees, judgments, civil or criminal fines, settlement amounts and other expenses customarily incurred in connection with legal proceedings. Under the indemnification agreements, a director or officer will not receive indemnification if he is found not to have acted in good faith in the reasonable belief that his action was in the best interests of the Company.

### CERTAIN TRANSACTIONS

Registration Rights. The Company is a party to a Registration Rights Agreement dated June 5, 1990, as amended (the "Registration Agreement"), with G & G Diagnostics Limited Partnership I and G & G Diagnostics Limited Partnership II (together, "G & G") pursuant to which G & G has certain rights to have its shares of Common Stock registered by the Company under the Securities Act. A total of 366,670 shares of Common Stock (the "Registrable Shares") held by G & G or subject to warrants held by G & G may be registered under the Registration Agreement. If the Company proposes to register any of its securities under the Securities Act, either for its own account or for the account of other securityholders. G & G is entitled to notice of the registration and is entitled to include, at the Company's expense, the Registrable Shares therein, provided, among other conditions, that the underwriters have the right to limit the number of such shares included in the registration. In addition, G & G may require the Company at its expense on no more than two occasions, to file a registration statement under the Securities Act with respect to its Registrable Shares, and the Company is required to use its best efforts to effect a registration. subject to certain conditions and limitations. Further, G & G may require the Company at its expense to register the Registrable Shares on Form S-3 when such form becomes available to the Company, subject to certain conditions and limitations. G & G waived its respective registration rights for this Offering. See "Principal Stockholders."

Warrant Exercise. In May 1995, G & G Diagnostics Limited Partnership II exercised warrants to purchase 40,000 shares of the Company's Common Stock for an exercise price of \$2.50 per share or an aggregate amount of \$100,000.

Indemnification Contracts. The Company intends to enter into indemnification agreements with each of its directors and officers. See "Management -- Limitation of Officers' and Directors' Liability; Indemnification Agreements."

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## PRINCIPAL STOCKHOLDERS

The following table sets forth certain information as of October 4, 1996 concerning the beneficial ownership of Common Stock by each director, certain executive officers, 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 received from or on behalf of the named individuals. Unless otherwise noted, the beneficial owners listed have sole voting and investment power over the shares listed. <TABLE>

<CAPTION>

Francis E. Capitanio(4)

# PERCENTAGE OF OUTSTANDING SHARES BENEFICIALLY OWNED(1)

NAME AND ADDRESS OF		OF SHARES AL OWNER	BEFORI BENE		AFTER THI LY OWNED	E OFFERING	OFFERING
<s></s>	<c></c>	<c></c>	<c></c>	>			
5% Stockholders							
Irwin J. Gruverman(2)		412,920	14.71%	9	.37%		
c/o G & G Diagnostics Limited P	artnership I						
30 Ossipee Road							
Newton, MA 02164							
G & G Diagnostics Limited Partne	ership II(3)	153,	333	5.69	3.57		
Directors and Senior Executives							
Richard T. Schumacher(4)(5)		1,013,957	35.8	9	22.91		
Henry A. Malkasian(4)(6)		311,510	11.54	7	7.24		
Kevin W. Quinlan(4)		93,100	3.37	2.13	3		
Patricia E. Garrett(4)		55,000	2.01	1.27			
Richard C. Tilton(4)		62,500	2.29	1.44			
Mark M. Manak(4)		55,500	2.03	1.28	3		
Barry M. Warren(4)		37,500	1.37	*			
Ronald V. DiPaolo(4)		28,000	1.03	*			
Calvin A. Saravis(4)		23,000	*	*			

8,750

- -----

- \* Less than 1% of the outstanding Common Stock.
- (1) The number of shares of Common Stock outstanding used in calculating the percentage for each listed person includes the shares of Common Stock underlying options or warrants held by such person.
- (2) Includes 283,333 shares held of record by three limited partnerships (including G & G Diagnostics Limited Partnership II), of which Mr. Gruverman is the general partner, 10,000 shares subject to options held by Mr. Gruverman and 106,670 shares subject to warrants held by one of three limited partnerships.
- (3) The address for G & G Diagnostics Limited Partnership II is the same as that for Mr. Gruverman. Mr. Gruverman is the beneficial owner of the shares of Common Stock held of record by G & G Limited Partnership II.
- (4) Includes the following shares subject to options: Mr. Capitanio -- 8,750, all of which are exercisable within 60 days after October 4, 1996; Dr. DiPaolo -- 28,000, 25,000 of which are exercisable within 60 days after October 4, 1996; Dr. Garrett -- 45,000, 41,250 of which are exercisable within 60 days after October 4, 1996; Mr. Quinlan -- 73,000, 58,000 of which are exercisable within 60 days after October 4, 1996; Mr. Malkasian -- 10,000, all of which are exercisable within 60 days after October 4, 1996; Dr. Manak -- 37,500, 26,250 of which are exercisable within 60 days after October 4, 1996; Dr. Saravis -- 23,000, all of which are exercisable within 60 days after October 4, 1996; Mr. Schumacher --135,000, 127,500 of which are exercisable within 60 days after October 4, 1996; Dr. Tilton -- 37,500, 26,250 of which are exercisable within 60 days after October 4, 1996; and Mr. Warren -- 37,500, 7,500 of which are exercisable within 60 days after October 4, 1996.
- (5) Includes 50,000 shares held of record by Mr. Schumacher's spouse and 20,000 shares held of record by Mr. Schumacher as custodian for his daughter. Excludes an aggregate of 144,067 shares held by other relatives of Mr. Schumacher as to which Mr. Schumacher disclaims beneficial ownership.
- (6) Includes 12,000 shares held of record by Mr. Malkasian's son, 5,000 shares held by Mr. Malkasian's daughter, 53,850 shares held by Mr. Malkasian's spouse and 30,000 shares held by Mr. Malkasian as trustee in trust for each of his son and his daughter.
- (7) Includes 4,000 shares held of record by Mr. Manak as custodian for his daughter.

</TABLE>

# DESCRIPTION OF CAPITAL STOCK

The authorized capital stock of the Company consists of 20,000,000 shares of Common Stock, \$0.01 par value (referred to herein as "Common Stock") and 1,000,000 shares of Preferred Stock, \$.01 par value (referred to herein as "Preferred Stock").

# COMMON STOCK

As of October 4, 1996, there were 2,690,064 shares of Common Stock outstanding, held of record by approximately 130 stockholders.

The holders of Common Stock are entitled to one vote per share on all matters to be voted on by stockholders and are entitled to receive such dividends, if any, as may be declared from time to time by the Board of Directors from funds legally available therefor. The holders of Common Stock do not have cumulative voting rights in the election of directors. Upon liquidation or dissolution of the Company, the holders of Common Stock are entitled to receive all assets available for distribution to the stockholders. The Common Stock has no preemptive or other subscription rights, and there are no

conversion rights or redemption or sinking fund provisions with respect to such shares. All of the shares of Common Stock are, and the shares to be sold in this Offering will be, fully paid and nonassessable.

### PREFERRED STOCK

The Company is authorized to issue up to 1,000,000 shares of Preferred Stock, none of which are outstanding. The Board of Directors may, without future action of the stockholders of the Company, issue the Preferred Stock in one or more classes or series and fix the rights and preferences thereof, including the dividend rights, dividend rates, conversion rights, voting rights, terms of redemption (including sinking fund provisions), redemption price or prices, liquidation preferences and the number of shares constituting any class or series, or the designations of such class or series. The voting and other rights of the holders of Common Stock may be subject to and adversely affected by, the rights of holders of any Preferred Stock that may be issued in the future.

### MASSACHUSETTS ANTI-TAKEOVER AND RELATED STATUTES

Control Share Acquisition Law. Under Chapter 110D of the Massachusetts General Laws governing "control share acquisitions," any stockholder of certain publicly-held Massachusetts corporations who acquires certain ranges of voting power -- one-fifth or more but less than one-third of all voting power, one-third or more but less than a majority of all voting power, or a majority or more of all voting power -- may not (except in certain transactions) vote such stock unless the stockholders (excluding the shares held by the interested stockholders) of the corporation so authorize. As permitted by Chapter 110D, the Company's Amended and Restated By-laws include a provision which excludes the Company from the applicability of that statute upon completion of the Offering.

Business Combination Statute. Chapter 110F of the Massachusetts General Laws, entitled "Business Combinations with Interested Shareholders," applies to publicly-held Massachusetts corporations with 200 or more stockholders of record. Generally, this statute prohibits such Massachusetts corporations from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date of the transaction in which the person becomes an interested stockholder unless (a) the interested stockholder obtains the approval of the corporation's board of directors prior to becoming an interested stockholder; (b) the interested stockholder acquires at least 90% of the voting stock of the corporation (excluding shares held by certain affiliates of the corporation) outstanding at the time he becomes an interested stockholder; or (c) the business combination is both approved by the board of directors and authorized at an annual or special meeting of stockholders by the holders of at least two-thirds of the outstanding voting stock of the corporation (excluding shares held by the interested stockholder). An "interested stockholder" is a person who, together with

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affiliates and associates, owns (or at any time within the prior three years did own) 5% or more of the outstanding voting stock of the Corporation. A "business combination" includes, among other transactions, a merger, stock or asset sale and other transactions resulting in a financial benefit to the stockholder. The Amended and Restated Articles of Organization and Restated By-laws of the Company do not expressly provide for opting out of the provisions of Chapter 110F. As a result, the application of this statute to the Company after completion of this Offering could discourage or make it more difficult for any person or group of persons to attempt to obtain control of the Company. The Company may at any time amend its Amended and Restated Articles of Organization or Restated By-laws to elect not to be governed by Chapter 110F, by a vote of the holders of a majority of its voting stock, but such an amendment would not be effective for twelve months and would not apply to a business combination with any person who became an interested stockholder prior to the date of the amendment.

# CERTAIN PROVISIONS OF THE COMPANY'S AMENDED AND RESTATED ARTICLES OF ORGANIZATION AND AMENDED AND RESTATED BY-LAWS

The Company's Amended and Restated Articles of Organization include several provisions which may render more difficult an unfriendly tender offer, proxy

contest, merger or other change in control of the Company. See "Risk Factors -- Possible Adverse Effect of Certain Anti-takeover Provisions."

Preferred Stock. The Amended and Restated Articles of Organization permit the Board of Directors to issue preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, without further vote or action by the stockholders. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of the Company and may adversely affect the voting and other rights of the holders of Common Stock. The Company currently has no plans to issue any preferred stock.

Classification of Board of Directors. The Amended and Restated Articles of Organization provide for the classification of the Company's Board of Directors into three classes, with the classes being elected for staggered three-year terms. At each annual meeting of stockholders, directors will be elected to succeed those in the class whose term then expires, and each elected director shall serve for a term expiring at the third succeeding annual meeting of stockholders after such director's election, and until the director's successor is elected and qualified. Thus, directors stand for election only once in three years. This provision also restricts the ability of stockholders to enlarge the Board of Directors. Changes in the number of Directors may be effected by a vote of a majority of the Continuing Directors (as defined in the Amended and Restated Articles of Organization) or by the stockholders by vote of at least 80% of the shares of the Company's voting stock outstanding, voting as a single class. Under this provision, Directors may only be removed with or without cause by the affirmative vote of the holders at least 80% of the combined voting power of the outstanding shares of the Company's voting stock, voting together as a single class, or upon the vote of a majority of the Continuing Directors.

Fair Price Provision. The Amended and Restated Articles of Organization contain a "Fair Price Provision" that is intended to protect stockholders who do not tender their shares in a takeover bid by guaranteeing them a minimum price for their shares in any subsequent attempt to purchase such remaining shares at a price lower than the acquiror's original acquisition price. The Fair Price Provision requires the affirmative vote of the holders of at least 80% of the Company's outstanding voting stock for certain business combinations with a Related Person, unless specified price criteria and procedural requirements are met or the business combination is approved by a majority of the Continuing Directors.

Indemnification Provision. The Amended and Restated Articles of Organization provide that the Company may, either in its By-laws or by contract, provide for the indemnification of directors, officers, employees and agents, by whomever elected or appointed, to the full extent permitted by applicable law, as it may be amended from time to time. See "-- Limitation of Officers' and Directors' Liability; Indemnification Agreements."

# TRANSFER AGENT AND REGISTRAR

The Transfer Agent and Registrar for the Common Stock is American Securities Transfer & Trust, Inc.

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# SHARES ELIGIBLE FOR FUTURE SALE

Prior to this Offering, there has been no public market for the Common Stock. Future sales of substantial amounts of Common Stock in the public market could adversely affect the market price of the Common Stock.

Upon completion of this Offering, the Company will have 4,290,064 shares of Common Stock outstanding (4,530,064 shares if the Underwriters' overallotment option is exercised in full). Of those shares, the 1,600,000 shares sold in this Offering (1,840,000 shares if the Underwriters' overallotment option is exercised in full) will be freely tradeable without restriction (except as to affiliates of the Company) or further registration under the Securities Act. The

remaining 2,690,064 shares of Common Stock were sold by the Company in reliance on exemptions from the registration requirements of the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act. All of the Company's directors and executive officers and certain other stockholders, holding in the aggregate 2,555,244 shares of Common Stock, have agreed not to offer to sell, sell or otherwise dispose of any shares of Common Stock prior to the expiration of 180 days from the date of this Prospectus. Oscar Gruss & Son Incorporated may, in its sole discretion and at any time without prior notice, release all or any portion of the shares of Common Stock subject to the lockup agreements.

Beginning 91 days after the date of this Prospectus, 6,475 shares of Common Stock will be eligible for sale in the public market without registration, subject to certain volume and other limitations, pursuant to Rule 144 or Rule 701 under the Securities Act of 1933, as amended (the "Securities Act") and an additional 122,571 shares will be eligible for sale without such restrictions. Following the expiration of the 180-day lockup period, an additional 1,643,197 shares of Common Stock will be eligible for sale in the public market without registration, subject to certain volume and other limitations, pursuant to Rule 144 or Rule 701 under the Securities Act and an additional 734,425 shares will be eligible for sale without such restrictions. The remaining shares of Common Stock held by existing stockholders will become eligible for sale under Rule 144 or otherwise at various times thereafter. All shares of Common Stock outstanding on the date of this Prospectus will be eligible for sale to certain qualified institutional buyers in accordance with Rule 144A under the Securities Act.

In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated), including an affiliate of the Company, may sell in the open market within any three-month period a number of shares that does not exceed the greater of (i) 1% of the then-outstanding shares of the Company's Common Stock or (ii) the average weekly trading volume in the over-the-counter market during the four calendar weeks preceding such sale, provided that a minimum of two years has elapsed between the later of the date of acquisition of the securities from the issuer or from an affiliate of the issuer. The holding period of shares of a non-affiliate for this purpose includes the holding period of all prior non-affiliate holders, provided that if an affiliate has held such shares at any time, the holding period shall commence upon the sale to a non-affiliate by the last affiliate to hold the shares. Sales under Rule 144 are also subject to certain limitations on the manner of sale, notice requirement and availability of current public information about the Company. Under Rule 144(k), a non-affiliate who holds restricted securities and who has not been affiliated with the Company during the three-month period preceding the proposed sale thereof may sell such securities without regard to conditions imposed by Rule 144 if at least three years have elapsed from the sale of such securities by the Company or any affiliate. The Securities and Exchange Commission has proposed amendments to Rule 144, including an amendment which would reduce the waiting period to one year.

Under Rule 701 of the Securities Act, persons who purchased shares pursuant to an employee stock purchase program or upon exercise of options granted prior to the effective date of this Offering are entitled, subject to certain conditions and limitations of Rule 701, to sell such shares 90 days after the effective date of this Offering in reliance upon Rule 144, without regard to the holding period requirement of Rule 144 and, in the case of non-affiliates, without compliance with the public information, volume limitation or notice provisions of Rule 144.

The Company intends to register under the Securities Act shortly after the consummation of the offering an aggregate of 1,647,600 shares of Common Stock issued or issuable upon exercise of employee stock options granted under the Non-Qualified Plan and the Employee Plan, including 934,387 shares issuable upon exercise of such options outstanding on the date of this Prospectus. Two of the Company's stockholders and the holder of a warrant to purchase Common Stock have the right to cause the Company to register their shares under the Securities Act and to include their shares in certain future registrations of securities effected by the Company under the Securities Act. An aggregate of 627,650 shares of Common Stock, including 226,670 shares of Common Stock issuable upon exercise of outstanding warrants are covered by such registration rights. See "Risk Factors -- Shares Eligible for Future Sale," "Certain Transactions -- Registration Rights" and "Principal Stockholders."

### UNDERWRITING

The Underwriters named below, for whom Oscar Gruss & Son Incorporated and Kaufman Bros., L.P. are acting as the Representatives (the "Representatives"), have severally agreed, subject to the terms and conditions contained in the Underwriting Agreement, to purchase from the Company the number of shares of Common Stock set forth opposite their respective names below.

<TABLE> <CAPTION>

The Underwriting Agreement provides that the several Underwriters are obligated to purchase all of the 1,600,000 shares of Common Stock offered by the Underwriters hereby (other than shares which may be purchased under the over-allotment option) if any are purchased. The Representatives have advised the Company that the Underwriters propose to offer the shares to the public initially at the public offering price set forth on the cover page of this Prospectus, that the Underwriters may allow to selected dealers a concession of \$\_\_\_\_\_ per share and that such dealers may reallow a concession of \$\_\_\_\_\_ per share to certain other dealers. After the initial public offering, the offering price and the concessions may be changed by the Representatives. The Representatives have informed the Company that the Underwriters do not intend to confirm sales to any accounts over which they exercise discretionary authority.

The Company has granted to the Underwriters an option, expiring at the close of business on the 30th day after the date of the Underwriting Agreement, to purchase up to 240,000 additional shares of Common Stock at the public offering price less underwriting discounts and commissions, all as set forth on the cover page of this Prospectus. The Underwriters may exercise the option only to cover over-allotments, if any, in the sale of shares of Common Stock in this Offering. To the extent that the Underwriters exercise the option, each Underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage thereof that the number of shares to be purchased by each of them as shown in the foregoing table bears to the 1,600,000 shares of Common Stock offered hereby.

The Company has agreed to pay to the Representatives a non-accountable expense allowance of one percent of the gross proceeds of the Offering (\$144,000 if the Underwriters' over-allotment option is not exercised and \$165,600 if the Underwriters' overallotment option is exercised in full, at an assumed public offering price of \$9.00 per share), of which \$40,000 has been paid to date. If the Offering is not consummated, the Representatives will return to the Company any unused portion of the pre-paid expense allowance. The Company has also agreed to pay all expenses in connection with registering or qualifying the Common Stock offered hereby for sale under the laws of the states in which the Common Stock is sold by the Underwriters (including expenses of counsel retained for such purposes by the Underwriters) as well as certain expenses associated with information meetings.

The Company has agreed to sell to the Representatives, or their designees, warrants (the "Underwriters' Warrants") to purchase 160,000 shares of the Company's Common Stock at an aggregate purchase price of \$\_\_\_\_\_\_. The exercise price per Underwriters' Warrant, subject to anti-dilution adjustment, is equal to 135% of the public offering price per share of Common Stock offered hereby. The Underwriters' Warrants expire on the fifth anniversary of the effective date of the Offering. The Underwriters' Warrants may not be transferred or exercised for one year from the date of this Prospectus, except for transfers to officers of the Representatives or members of the underwriting or selling group and/or

partners, if any. The Underwriters' Warrants become exercisable during the four-year period commencing one year from the date of this Prospectus (the "Warrant Exercise Term"). During the Warrant Exercise Term, the holders of the Underwriters' Warrants are given, at nominal cost, the opportunity to profit from an increase in the market price of the Company's Common Stock. The Company has granted the Representatives certain demand and "piggyback" registration rights with respect to the Underwriters' Warrants. Demand registration rights will expire five years from the effective date of the Offering, and the Company shall be required to effect such registration on one occasion only. "Piggyback" registration rights will terminate seven years from the effective date of the Offering.

Except as set forth below, the Company, its officers and directors, and certain of its stockholders, who will hold an aggregate of 2,555,244 shares after this Offering, have agreed that they will not, directly or indirectly, offer, sell, offer to sell, contract to sell, grant any option to purchase or otherwise sell or dispose of any shares of Common Stock or other capital stock of the Company or any securities convertible into, or exercisable or exchangeable for, any shares of Common Stock or other capital stock of the Company for a period of 180 days after the date of this Prospectus without the prior written consent of Oscar Gruss & Son Incorporated on behalf of the Underwriters. Oscar Gruss & Son Incorporated may, in its sole discretion and at any time without prior notice, release all or any portion of the shares of Common Stock subject to these "lock-up" agreements.

Prior to this Offering, there has not been any public market for the Common Stock. Consequently, the initial public offering price of the Common Stock offered hereby will be determined through negotiations between the Company and the Representatives. Among the factors to be considered in making such determination will be the prevailing market conditions, the Company's fiscal and operating history and condition, the Company's prospects and the prospects of its industry, the management of the Company, the market price for securities for companies in businesses similar to that of the Company and the recent trading activity and prices of shares of common stock on the Nasdaq National Market. The estimated initial public offering price range set forth on the cover page of this Prospectus is subject to change as a result of market conditions and other factors. See "Risk Factors -- No Assurance of Public Market; Volatility of Stock Price."

Kaufman Bros., L.P. became registered as a broker-dealer in July 1995 and has participated in a limited number of public offerings as an underwriter. See "Risk Factors -- Lack of Underwriting History."

The Company has agreed to indemnify the Underwriters against certain liabilities, including liabilities under the Securities Act.

# LEGAL MATTERS

Certain legal matters in connection with this Offering will be passed upon for the Company by Brown, Rudnick, Freed & Gesmer, Boston, Massachusetts. Certain legal matters in connection with the Common Stock offered hereby will be passed upon for the Underwriters by Fulbright & Jaworski L.L.P., New York, New York. A member of Brown, Rudnick, Freed & Gesmer, counsel to the Company, is Clerk and is the owner of 12,000 shares of the Company's Common Stock.

## **EXPERTS**

The consolidated balance sheets of Boston Biomedica, Inc. and Subsidiaries as of December 31, 1994 and 1995 and the consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 1995, included in this prospectus, have been included herein

in reliance on the report of Coopers & Lybrand L.L.P., independent accountants, given on the authority of that firm as experts in accounting and auditing.

### ADDITIONAL INFORMATION

The Company has filed with the Securities and Exchange Commission (the "Commission"), Washington, D.C. 20549, a Registration Statement on Form S-1 (the "Registration Statement") under the Securities Act with respect to the Common Stock offered hereby. This Prospectus does not contain all of the information set forth in the Registration Statement and the exhibits and schedules thereto. For

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further information with respect to the Company and the Common Stock, reference is made to the Registration Statement and the exhibits and schedules thereto. Statements contained in this Prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance where such contract or document is filed as an exhibit to the Registration Statement, reference is made to the copy of such contract or document filed as an exhibit to the Registration Statement, each such statement being qualified in all respects by such reference. A copy of the Registration Statement may be inspected without charge at the offices of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549, and at the Commission's regional offices located at Seven World Trade Center, 13th Floor, New York, New York 10048, and at 500 West Madison Street, Northwestern Atrium Center, Suite 1400, Chicago, Illinois 60661-2511. Copies of materials can also be obtained at prescribed rates from the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549. The Commission maintains a World Wide Web site on the Internet at http://www.sec.gov that contains registration statements, reports, proxy and information statements and other information regarding registrants that file electronically with the Commission.

The Company intends to distribute to its stockholders annual reports containing consolidated financial statements audited by its independent accountants and will make available copies of quarterly reports for the first three quarters of each fiscal year containing unaudited consolidated financial information.

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# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES INDEX TO FINANCIAL STATEMENTS

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Report of Coopers & Lybrand L.L.P., Independent Accountants

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Consolidated Balance Sheets as of December 31, 1994 and 1995 and June 30, 1996 (unaudited) F-3

Consolidated Statements of Operations for the years ended December 31, 1993, 1994, and 1995 and for the six months ended June 30, 1995 (unaudited) and June 30, 1996 (unaudited)

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Consolidated Statements of Stockholders' Equity for the years ended December 31, 1993, 1994, and 1995 and for the six months ended June 30, 1996 (unaudited)

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Consolidated Statements of Cash Flows for the years ended December 31, 1993, 1994, and 1995 and for the six months ended June 30, 1995 (unaudited) and June 30, 1996 (unaudited) F-6

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### REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Stockholders of BOSTON BIOMEDICA, INC.:

We have audited the accompanying consolidated balance sheets of Boston Biomedica, Inc. and Subsidiaries as of December 31, 1994 and 1995 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1995. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with generally accepted auditing standards. Those standards 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. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Boston Biomedica, Inc. and Subsidiaries as of December 31, 1994 and 1995 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 1995 in conformity with generally accepted accounting principles.

COOPERS & LYBRAND L.L.P.

Boston, Massachusetts March 12, 1996, except as to the information in the first paragraph of Note 11, for which the date is September 10, 1996

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# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

<TABLE> <CAPTION>

<S><C> <C> < C >ASSETS **CURRENT ASSETS:** \$ 89,129 \$ 11,463 \$ 10,548 \$ 10,548 Cash Accounts receivable, less allowances of \$94,723 in 1994, \$142,372 in 1995 and \$133,579 in 1996 2,259,842 3,075,870 2,866,401 2,866,401 3,609,516 3,676,851 3,865,219 3,865,219 Inventories (Notes 1 & 3) Prepaid expense and other 156,117 254,199 294,646 294,646 Deferred income taxes (Note 7) 101,880 110,766 213,538 213,538 Total current assets 6,216,484 7,129,149 7,250,352 7,250,352 ..... -----Property and equipment, net (Notes 1 & 4) 1,724,420 2,614,982 2,625,117 2,625,117 OTHER ASSETS: Notes receivable and other 22,079 83,422 79.037 79,037 Goodwill and other intangibles, net (Notes 1 & 2) 112,521 100,820 92,777 92,777 134,600 184,242 171,814 171,814 TOTAL ASSETS \$8,075,504 \$9,928,373 \$10,047,283 \$10,047,283 LIABILITIES AND STOCKHOLDERS' EOUITY CURRENT LIABILITIES: Current maturities of long term debt (Note 6) \$ 242,006 \$ 436,509 \$ 490,126 \$ 490,126 787,406 745,216 815,946 815,946 Accounts payable Accrued compensation 361,911 395,755 488,223 488,223 Other accrued expenses 199,334 139.052 127.712 127,712 Deferred revenue 523,401 831,244 831,244 Total current liabilities 1,530,375 2,300,215 2,753,251 2,753,251 LONG-TERM LIABILITIES: Long-term debt, less current maturities (Note 6) 3,179,526 4,215,501 2,797,581 2,797,581 e 6) 3,179,526 4,215,501 2,797,58 186,860 141,068 107,832 107,832 Deferred rent Deferred income taxes (Note 7) 137,520 84,641 157,899 COMMITMENTS AND CONTINGENCIES (Note 8) REDEEMABLE COMMON STOCK (Note 11) \$.01 par value; 117,647 shares authorized, issued and 898,503 outstanding STOCKHOLDERS' EQUITY (Note 10): Common stock, \$.01 par value; authorized 15,000,000 shares in 1994, 1995 and 1996; issued and outstanding 2,578,865 in 1994; issued 2,640,417 in 1995; issued and outstanding 2,572,417 in 1996 actual and 26,404 25,789 2,690,064 pro forma 25,724 26,901 2,612,500 2,798,620 2,717,700 3,615,026 Additional paid-in capital Retained earnings 402,934 505,924 588,793 588,793 3,041,223 3,330,948 3,332,217 4,230,720 Less treasury stock, at cost -- 80,000 shares -- (144,000) Total stockholders' equity 3,041,223 3,186,948 3,332,217 4,230,720 \_\_\_\_\_ TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY \$ 8,075,504 \$9,928,373 \$10,047,283 \$10,047,283

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

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</TABLE>

<TABLE> <CAPTION> YEARS ENDED DECEMBER 31, SIX MONTHS ENDED JUNE 30, 1993 1994 1995 1995 1996 (UNAUDITED) <S><C> <C> <C> <C> <C> REVENUE: Product sales \$ 3,942,328 \$ 5,981,378 \$ 6,621,631 \$ 3,024,629 \$ 3,945,759 5,214,688 4,741,376 5,649,099 2,539,851 2,982,624 Services 9,157,016 10,722,754 12,270,730 5,564,480 6,928,383 Total revenue COSTS AND EXPENSES: Cost of product sales 2,087,771 3,194,217 3,564,241 1,646,594 2,006,833 Cost of services 3,965,154 3,415,777 4,167,625 1,960,315 2,249,610 Research and development 278,859 469,358 375,712 159,035 361,619 894,202 1,191,573 1,339,792 637,567 915,289 1,619,331 2,047,256 2,315,814 1,056,590 1,088,448 Selling and marketing General and administrative Total operating costs and expenses 8,845,317 10,318,181 11,763,184 5,460,101 6,621,799

Income from operations 311,699 404,573 507,546 104,379 306,584 311,699 404,573 507,546 104,3° 178,640 243,694 335,899 164,569 Interest expense, net 168,469 ------Income (loss) before income taxes and extraordinary item 133,059 160,879 171,647 (60,190)138,115 (Provision) benefit (for) from income taxes (Notes 1 & 7) (40,473) (64,351) (68,657)24,034 (55,246)\_\_\_\_\_\_ Income (loss) before extraordinary item 92,586 96,528 102,990 (36,156)82.869 -----Extraordinary item-gain on elimination of debt (Notes 6 & 7), net of income taxes of \$33,157 49,736 -- --Net income (loss) \$ 142,322 \$ 96,528 \$ 102,990 \$ (36,156) \$ 82,869 Income (loss) per share: Before extraordinary gain \$ 0.04 \$ 0.04 \$ 0.04 \$ (0.01) \$ Extraordinary gain 0.02 -- -- --Net income (loss) \$ 0.06 \$ 0.04 \$ 0.04 \$ (0.01) \$ 0.03 Weighted average common and common equivalent shares outstanding 2,437,725 2,587,137 3,151,477 2,597,590 3,252,643 </TABLE>

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

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

<TABLE> <CAPTION>

COMMON STOCK

ADDITIONAL TOTAL
\$.01 PAR PAID-IN RETAINED TREASURY STOCKHOLDERS'
SHARES VALUE CAPITAL EARNINGS STOCK EQUITY

<s> <c></c></s>	<c> <c> <c> <c> <c></c></c></c></c></c>
BALANCE, December 31, 1992	2,280,040 \$ 22,800 \$ 1,635,830 \$ 164,084 \$ 1,822,714
Issuance of common stock	201,298 2,013 711,318 713,331
Stock options and warrants exercised	33,000 330 65,420 65,750
Conversion of note payable	10,690 107 17,532 17,639
Net income	142,322 142,322
BALANCE, December 31, 1993	2,525,028 25,250 2,430,100 306,406 2,761,756
Issuance of common stock	29,862 299 139,403 139,702
Stock options and warrants exercised	23,975 240 30,197 30,437
Tax benefit of stock options exercised	12,800 12,800
Net income	96,528 96,528
BALANCE, December 31, 1994	2,578,865 25,789 2,612,500 402,934 3,041,223
Issuance of common stock	8,535 85 58,160 58,245
Stock options and warrants exercised	47,200 472 117,068 117,540
Conversion of note payable	5,817 58 9,542 9,600
Treasury stock purchased 80,000 sha	res \$ (144,000) (144,000)
Tax benefit of stock options exercised	1,350 1,350
Net income	102,990 102,990
BALANCE, December 31, 1995	2,640,417 26,404 2,798,620 505,924 (144,000) 3,186,948
Stock options and warrants exercised	
(unaudited) 12,0	
Issuance of treasury stock 80,000 sha	ires
(unaudited) (80,0	000) (800) (143,200) 144,000
Net income (unaudited)	82,869 82,869
BALANCE, June 30, 1996 (unaudited)	2,572,417 \$ 25,724 \$ 2,717,700 \$ 588,793 \$ 3,332,217
	=======================================

  |</TABLE>

Accounts payable

Accrued expenses

Deferred revenue

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

<TABLE> <CAPTION> YEARS ENDED DECEMBER 31, SIX MONTHS ENDED JUNE 30, 1993 1994 1995 1995 1996 (UNAUDITED) <S><C> <C> <C> CASH FLOWS FROM OPERATING ACTIVITIES: Net income (loss) \$ 142,322 \$ 96,528 \$ 102,990 \$ (36,156) \$ Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities: 301.004 Depreciation and amortization 360,512 441,356 202,693 280,426 Provision for doubtful accounts 22,956 102,099 181,084 53,643 77,145 Deferred rent 99,708 5,908 (45,792)(12,556)(33,236)Deferred income taxes 42,323 (42,798)(61,765)(74,809)(29,514)Tax benefit of stock options exercised 12,800 1,350 Extraordinary item-gain on elimination of debt (49,736) Changes in operating assets and liabilities: Accounts receivable (215,270) (529,157) (997,112)11,403 132,324 (12,962)Note receivable and other assets (17,002)(3,720)(61,343)4,385 Inventories (950,715) (567,420) (188,368)(67,335)77,857 Prepaid expenses 25,410 (3,500)(98,082)(79,496)(40,447)

(86,130)

100,767

523,401

11.875

160,021

(42,190)

94,126

35.834

(60,639)

307,843

70,730

20,846

Net cash (used in) provided by cactivities	perating (427,104) (554,111) (29,312) 104,812 685,003
Purchase of intangible assets Net assets of acquisitions (net of ca	nt (460,591) (404,639) (1,316,217) (215,542) (282,518) (4,000)
Net cash used in investing activi	ties (850,294) (404,639) (1,320,217) (215,542) (282,518)
Proceeds from redeemable commo Proceeds of common stock issued, Repayments of long-term debt	ACTIVITIES:  1,107,392 1,734,425 1,517,867 191,990 226,300  n stock, net 898,503  net 765,081 170,139 175,785 103,126 62,400  (613,199) (887,989) (277,789) (1,590,603)  (144,000) (144,000)
Net cash (used in) provided by f activities	inancing 1,259,274 1,016,575 1,271,863 151,116 (403,400)
	H: (18,124) 57,825 (77,666) 40,386 (915) 49,428 31,304 89,129 89,129 11,463
Cash, end of period	\$ 31,304 \$ 89,129 \$ 11,463 \$ 129,515 \$ 10,548

# SUPPLEMENTAL DISCLOSURES OF NONCASH

**ACTIVITIES:** 

Conversion of note payable to common stock \$ 17,639 -- \$ 9,600 \$ 9,600

## SUPPLEMENTAL INFORMATION:

Income taxes paid \$ 10,689 \$ 33,718 \$ 168,994 \$ 129,100 \$ 85,000 Interest paid \$ 163,831 \$ 254,133 \$ 331,495 \$ 163,735 \$ 178,328 </TABLE>

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

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BOSTON BIOMEDICA, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (INFORMATION AS OF JUNE 30, 1996 AND FOR THE SIX MONTHS ENDED JUNE 30, 1996 AND 1995 IS UNAUDITED.)

# (1) BUSINESS AND SIGNIFICANT ACCOUNTING POLICIES

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

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, Biotech Research Laboratories, Inc. ("BTRL") and BBI-North American Clinical Laboratories, Inc. ("BBI-NACL"). All significant intercompany accounts and transactions have been eliminated in the consolidation.

# (ii) Reclassification

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

## (iii) Use of Significant Estimates

To prepare the financial statements in conformity with generally accepted accounting principles, management is required to make 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. Actual results could differ from the estimates and assumptions used by management.

# (iv) Revenue Recognition

Product revenues are recognized as sales 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, and transfer to the customers of all risks and rewards of ownership. Accounts receivable as of December 31, 1995 and June 30, 1996 include bill and hold receivables of \$179,000 and \$85,000, respectively. There were no such receivables as of December 31, 1993 and 1994.

The Company periodically enters into barter transactions whereby the Company exchanges inventory for testing services. Revenue on these transactions are recognized when both the products have been shipped and the testing services have been completed and are recorded at the estimated fair market value of the inventory based upon standard Company prices. The revenue recognized on these transactions for the years ended December 31, 1993, 1994 and 1995 and for the six months ended June 30, 1995 and 1996 was \$30,000, \$192,000, \$213,000, \$126,000 and \$191,000, respectively.

Services are recognized as revenue upon completion of tests for specialty laboratory services.

Revenue under long-term contracts, including funded research and development contracts, is recorded under the percentage of completion method, wherein costs plus profit is recorded as service revenue and billed monthly as the work is performed. Certain customers make advance payments that are deferred until revenue recognition is appropriate. Unbilled amounts for fee retainage are included in accounts receivable at

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BOSTON BIOMEDICA, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED) (INFORMATION AS OF JUNE 30, 1996 AND FOR THE SIX MONTHS ENDED JUNE 30, 1996 AND 1995 IS UNAUDITED.)

# (1) BUSINESS AND SIGNIFICANT ACCOUNTING POLICIES -- (CONTINUED)

December 31, 1994, 1995, and June 30, 1996, and are immaterial. When the current contract estimates indicate a loss, provision is made for the total anticipated loss. The Company does not believe there are any material collectability issues associated with these receivables.

Total revenue related to funded research and development contracts was approximately \$1,721,000, \$660,000, \$728,000, \$278,000 and \$598,000 for the years ended December 31, 1993, 1994 and 1995 and for the six months ended June 30, 1995 and 1996, respectively. Total contract costs associated with these agreements were approximately \$1,392,000, \$511,000, \$575,000, \$219,000 and \$553,000 for the years ended December 1993, 1994 and 1995 and for the six months ended June 30, 1995 and 1996, respectively.

# (v) Research and Development Costs

Research and development costs are expensed as incurred.

(vi) Inventories

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

## (vii) Property and Equipment

Property and equipment are stated at cost. For financial reporting purposes, depreciation is recognized using accelerated and straight-line methods, allocating the cost of the assets over their estimated useful lives ranging from five years to ten years for certain manufacturing and laboratory equipment, and fifteen years for the building. Upon retirement or sale, the cost and related accumulated depreciation of the asset are removed from the books. Any resulting gain or loss is credited or charged to income.

## (viii) Goodwill and Intangibles

Goodwill results from excess of the purchase prices over the net assets of BTRL and BBI-NACL acquired and is amortized on a straight line basis over ten years. Other intangibles primarily consist of patents, licenses, and intellectual property rights and are amortized over five to ten years.

### (ix) Income Taxes

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

# (x) Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk are principally cash and accounts receivable. The Company places its cash in federally chartered banks, each of which is insured up to \$100,000 by the Federal Deposit Insurance Corporation. Concentration of credit risk with respect to accounts receivable is limited to certain customers to whom the Company

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BOSTON BIOMEDICA, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED) (INFORMATION AS OF JUNE 30, 1996 AND FOR THE SIX MONTHS ENDED JUNE 30, 1996 AND 1995 IS UNAUDITED.)

# (1) BUSINESS AND SIGNIFICANT ACCOUNTING POLICIES -- (CONTINUED)

makes substantial sales. 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.

# (xi) Interim Consolidated Financial Statements

The consolidated financial statements as of June 30, 1996 and for the six months ended June 30, 1995 and 1996 and related footnote information are unaudited and have been prepared on a basis substantially consistent with the audited consolidated financial statements, and, in the opinion of management, include all adjustments (consisting of only normal recurring adjustments) necessary for fair presentation of the results of these interim periods. The results of the six months ended June 30, 1996 are not necessarily indicative of the results to be expected for the entire year.

## (xii) Deferred Revenue

Deferred revenue consists of payments received from customers in advance of

### (xiii) Computation of Income (Loss) Per Share

Net income (loss) per common share is computed based upon the weighted average number of common shares and common equivalent shares (using the treasury stock method) outstanding after certain adjustments described below. Common equivalent shares consist of common stock options and warrants outstanding. In accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 83, all common, redeemable common, and common equivalent shares issued during the twelve month period prior to the proposed date of the initial filing of the Registration Statement have been included in the calculation as if they were outstanding for all periods using the treasury stock method and assuming an initial public offering price of \$9.00 per share. Fully diluted net income (loss) per common share is not presented as it does not differ from primary earnings per share.

## (xiv) Recent Accounting Pronouncements

In March 1995, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of" ("SFAS 121"). SFAS 121 requires that an impairment loss be recognized for long-lived assets and certain identified intangibles when the carrying amount of these assets may not be recoverable. The Company has adopted SFAS 121 effective in 1996 and the adoption did not have a material impact on the financial statements.

In October 1995, the FASB issued Statement of Financial Accounting Standards No. 123 ("SFAS 123") "Accounting for Stock-Based Compensation," which becomes effective for fiscal years beginning after December 15, 1995. SFAS 123 establishes new financial accounting and reporting standards for stock-based compensation plans. However, entities are allowed to elect whether to measure compensation expense for stock-based compensation under SFAS 123 or APB No. 25, "Accounting for Stock Issued to Employees." The Company has elected to continue to account under APB No. 25 and will make the required pro forma disclosures of net income and earnings per share as if the provisions of SFAS 123 had been applied in its December 31, 1996 financial statements. The potential impact of adopting this standard on the Company's pro forma disclosures of net income and earnings per share has not been quantified at this time.

## (xv) Pro Forma Presentation (Unaudited)

As discussed further in Note 11, completion of a public offering will terminate the redemption feature of the Redeemable Common Stock and cause its reclassification into 117,647 shares of common stock. The unaudited pro forma balance sheet has been prepared assuming the reclassification of the Redeemable Common Stock into common stock as of June 30, 1996.

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BOSTON BIOMEDICA, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED) (INFORMATION AS OF JUNE 30, 1996 AND FOR THE SIX MONTHS ENDED JUNE 30, 1996 AND 1995 IS UNAUDITED.)

# (2) ACQUISITION

Effective January 1, 1993, North American Laboratory, Inc., a Massachusetts corporation and wholly-owned subsidiary of BBI, acquired the net assets of North American Laboratory Group, Ltd., Inc. from its founder and chief scientific officer, who remains in this same capacity. During 1995, the name was changed to BBI-North American Clinical Laboratories, Inc. BBI-NACL is a specialty infectious disease testing laboratory providing testing services to hospitals and other health care providers. The purchase price was \$425,000 in cash representing \$375,038 of net tangible assets (including cash of \$35,297) and \$49,962 of goodwill and other intangibles.

### (3) INVENTORIES

The Company purchases human plasma and serum from various private and commercial blood banks. Upon receipt, such purchases generally undergo comprehensive testing, and associated costs are included in the value of raw materials. Most plasma is manufactured into Basematrix and other diagnostic components to customer specifications. Plasma and serum with the desired antibodies or antigens are sold or manufactured into Quality Control Panels, Accurun(tm) 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.

Inventories consist of the following:

```
<TABLE>
<CAPTION>
                DECEMBER 31,
               1994
                       1995
                                JUNE 30, 1996
                            (UNAUDITED)
                         <C>
\langle S \rangle
                               <C>
                  $ 1,548,560 $ 1,298,131
Raw materials
                                         $ 1,272,687
Work-in-process
                     551,280
                              565,667
                                           597,922
                   1,509,676 1,813,053
                                           1,994,610
Finished goods
             $ 3,609,516 $ 3,676,851 $ 3,865,219
</TABLE>
```

# (4) PROPERTY AND EQUIPMENT

Property and equipment at December 31, 1994 and 1995 consist of the following:

```
<TABLE>
<CAPTION>
                      1994
                               1995
<S>
                       <C>
                               <C>
                             $1,442,349 $1,630,872
Laboratory equipment
Management information systems
                                 609,923 834,768
Office equipment
                            249,544 332,496
Automobiles
                           176,315 178,465
Leasehold improvements
                                300,341
                                          108,892
Land, building and improvements
                                --
                                          941,175
                     2,778,472 4,026,668
Less accumulated depreciation
                              1,054,052 1,411,686
                          $1,724,420 $2,614,982
Net book value
```

Depreciation expense for the years ended December 31, 1993, 1994 and 1995 and the six months ended June 30, 1995 and 1996 was \$286,456, \$345,228, \$425,655, \$194,236 and \$272,383, respectively.

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</TABLE>

### (5) REVENUE FROM SIGNIFICANT CUSTOMERS AND EXPORT SALES

The Company performs contract research and certain services under contracts, subcontracts and grants from United States Government Agencies, primarily the National Institutes of Health ("NIH"). Revenue from such contracts, subcontracts and grants was approximately \$2,707,000 in 1993, \$1,677,000 in 1994, and \$1,628,000 in 1995.

Export sales accounted for approximately \$1,411,000, or 15% of consolidated revenue in 1993; \$2,279,000, or 21% in 1994; \$3,104,000, or 25% in 1995; and \$1,523,000, or 27%, and \$1,877,000, or 27% for the six months ended June 30, 1995 and 1996, respectively.

## (6) LONG TERM DEBT

In August 1995, the Company's revolving line of credit ("Revolver") was increased to \$3,500,000 and the due date extended to June 30, 1997. In July 1996, the due date of the Company's Revolver was extended to June 30, 1998, and the interest rate reduced to prime plus 1/2 %. In addition, the Company borrowed \$200,000 under a five-year term loan approved in 1994 (\$170,370 outstanding at December 31, 1995), \$100,000 under a five-year term loan, and \$123,700 under a \$350,000 five year term loan facility for equipment acquisitions approved in 1995 ("New Term"). As of December 31, 1995, the Company had additional borrowing capacity available under the New Term facility equal to \$226,300. The Company borrowed this amount prior to the facility expiration date of May 2, 1996. In July 1996, the Company received approval for a \$250,000, five year equipment facility loan from its bank due July 31, 2001 at a rate of prime plus 1%.

Borrowings under the Revolver are limited to 80% of eligible accounts receivable plus the lesser of 40% of inventory or \$1,500,000. The Company had approximately \$657,000 and \$2,028,000 available under it's Revolver as of December 31, 1995 and June 30, 1996, respectively. Amounts outstanding under the Revolver bear interest at the lender's base rate plus 1% (9.75% at December 31, 1995 and 9.25% at June 30, 1996) and are collateralized by all of the Company's assets and a \$2 million life insurance policy of an officer/stockholder.

The Revolver contains covenants regarding the Company's debt-to-equity ratio and certain minimum debt service coverage ratios. The Revolver further provides for restrictions on the payment of dividends, limitations on the acquisition of property and equipment, limitations on additional borrowings, and certain minimum stock ownership levels by the officer/stockholder referred to above.

In December 1995, the Company purchased its corporate headquarters and manufacturing facility in West Bridgewater, MA from its former landlord at a price of \$806,800 including closing costs, and borrowed \$750,000 from its bank to finance the purchase. See also Note 4.

On June 30, 1993, the Company exercised its option to pre-pay the acquisition note in connection with the 1992 purchase of BTRL at a substantial discount from the balance due, resulting in an extraordinary gain of \$49,736 (\$82,893 minus taxes of \$33,157).

During 1993, convertible debt in the amount of \$17,639 was converted into 10,690 shares of common stock at a price of \$1.65 per share. During 1995, convertible debt in the amount of \$9,600 was converted into 5,817 shares of common stock at a price of \$1.65 per share.

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BOSTON BIOMEDICA, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED) (INFORMATION AS OF JUNE 30, 1996 AND FOR THE SIX MONTHS ENDED JUNE 30, 1996 AND 1995 IS UNAUDITED.)

## (6) LONG TERM DEBT -- (CONTINUED)

At December 31, 1994 and 1995, and June 30, 1996, the Company had the following debt outstanding:

<CAPTION>

JUNE 30, 1994 1995 1996

(UNAUDITED)

Revolving Line of Credit Agreement due June 30, 1998 \$2,533,860 \$2,784,307 \$1,397,884

Note payable to a bank, due in monthly principal payments of \$17,687 through October 1998 with interest fixed at 9.01%. Collateralized by all of the

assets of the Company 813,625 601,375 495,250

Note payable to a bank, due in monthly principal payments of \$3,704 through October 1999 with interest at prime rate plus 1.0%. Collateralized by all of the assets of

the Company -- 170,370 148,148

Note payable to a bank, due in monthly principal payments of \$1,667 through December 2000 with interest at 8.22%.

Collateralized by all of the assets of the Company -- 100,000 91,667

Note payable to a bank, with interest only due until May 2, 1996, and thereafter 54 consecutive equal monthly principal payments of \$6,863 commencing June 18, 1996. Interest is at prime rate plus 1.0%. Collateralized by

all of the assets of the Company -- 123,700 343,137

Note payable to a bank, due in 84 fixed payments of principal and interest of \$11,729, bearing interest fixed at 8.30% for the first five years, and floating at prime plus 1.0% for the remaining term. Collateralized by a mortgage and all of the assets of the Company.

all of the assets of the Company -- 750,000 705,580

Subordinated convertible note payable, at 12.5% interest rate, due December 31, 1996, interest payable monthly. Convertible into common stock at \$1.50 per share at the option of the holder.

option of the holder 31,100 21,500 21,500

Other installment notes payable with interest rates ranging from 7.25% to 10.99% at December 31, 1995, collateralized by office equipment and vehicles due at various maturity

dates from April 1996 to August 2001 42,947 100,758 84,541

Total long term debt 3,421,532 4,652,010 3,287,707 Less: current maturities (242,006) (436,509) (490,126)

\$3,179,526 \$4,215,501 \$2,797,581

</TABLE>

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BOSTON BIOMEDICA, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED) (INFORMATION AS OF JUNE 30, 1996 AND FOR THE SIX MONTHS ENDED JUNE 30, 1996 AND 1995 IS UNAUDITED.)

(6) LONG TERM DEBT -- (CONTINUED)

At December 31, 1995, debt maturities are as follows:

<TABLE>

<CAPTION>

YEAR ENDED AMOUNT

	=======================================
	\$4,652,010
Thereafter	260,221
2000	161,382
1999	207,300
1998	386,723

</TABLE>

# (7) INCOME TAXES

The Company's effective tax rate does not significantly differ from the federal and state income tax statutory rates. The components of the provision for income taxes are as follows:

<TABLE> <CAPTION> 1993 1994 1995 <S> <C> <C>  $\langle C \rangle$ Current expense: federal and state \$ 23,700 \$ 91,242 \$ 130,422 Deferred (benefit) expense: federal and state 49,930 (26,891) (61,765)Total \$ 73,630 \$ 64,351 \$ 68,657 ==: </TABLE>

The provision for 1993 includes \$33,157 of income taxes which was offset against the extraordinary gain on elimination of debt of \$82,893 and presented net in the Statement of Operations. See also Notes 2 and 6.

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

<TABLE> <CAPTION> 1994 1995 <S><C> <C> Current deferred taxes: \$ 47,318 Inventory Allowances and other accruals 54,562 \$ 110,766 Total deferred tax assets 101,880 110,766 Long term deferred taxes: Accelerated tax depreciation (163,139) (207,361)Cash basis benefit of subsidiary (47,818)Goodwill (26,859) (22,795)Tax credits 100,296 106,710 State net operating loss carryforwards 38,805 Total deferred tax liabilities (137,520) (84,641) Total net deferred tax (liabilities) assets \$ (35,640) \$ 26,125

</TABLE>

As of December 31, 1995, the net operating loss carryforwards expire at various dates beginning in 1998 through 2000. Tax credits expire at various dates beginning in 2006 through 2009.

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## (8) COMMITMENTS AND CONTINGENCIES

The Company leases certain office space, laboratory, and research facilities under operating leases with various terms through July 2000. All the real estate leases include renewal options at increasing levels of rent.

One of the facility leases includes scheduled base rent increases over the term of the lease. The amount of base rent payments is being charged to expense on the straight-line method over the term of the lease. As of December 31, 1995, the Company has recorded a \$141,068 noncurrent liability 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 above facilities.

Rent expense for the years ended December 31, 1993, 1994 and 1995 and six months ended June 30, 1995 and 1996 was \$479,697, \$549,713, \$477,580, \$225,109 and \$181,816, respectively. At December 31, 1995, the remaining fixed lease commitment was as follows:

<table></table>	
<caption></caption>	
YEAR ENDED	AMOUNT
<s></s>	<c></c>
1996	\$371,200
1997	254,600
1998	117,300
1999	124,800
2000	79,700
	\$947,600
	======

  |Commencing in February 1995, the Company committed under a sponsored research agreement with a university to fund a research scientist at a cost of \$13,125 per quarter for three years which costs are charged to research and development expense. In return, the Company has exclusive rights to any anti-HIV compounds or derivatives developed in the course of this research, provided the Company obtains certain regulatory approvals from the FDA.

# (9) 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 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. To date, the Company has made no contributions to the plan.

# (10) COMMON STOCK

The Company has two stock option plans which are administered by a committee of the Board of Directors who determines the employees and affiliated persons to receive options and the number and option price of shares covered by each such option.

Options granted under both plans may be either incentive stock options or non-qualified stock options. In general, for incentive stock options, the option price shall not be less than the fair market value at the time the option is granted. 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 issued expire ten years from the date of grant, or 30 days from the date of termination or affiliation.

At December 31, 1995, 897,600 shares have been reserved for non-qualified stock options, of which 97,125 are available for future grants. At December 31, 1995, 750,000 shares have been reserved for incentive stock options, of which 696,812 are available for future grants.

# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED) (INFORMATION AS OF JUNE 30, 1996 AND FOR THE SIX MONTHS ENDED JUNE 30, 1996 AND 1995 IS UNAUDITED.)

# (10) COMMON STOCK -- (CONTINUED)

The Company has issued warrants in connection with certain equity and debt financings. As of June 30, 1996, 226,670 shares of Common Stock have been reserved for issuance pursuant to the exercise of such warrants at a weighted average exercise price of \$2.50 per share.

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

<table> <caption></caption></table>	
	STOCK OPTIONS WARRANTS
	PRICE PRICE TOTAL SHARES PER SHARE SHARES
<\$> Balance outstanding, December Granted Exercised Expired	C> C
Balance outstanding, December Granted	per 31, 1993 881,850 .25-4.50 306,138 2.00-5.20 1,187,988
Exercised Expired	(19,375) .25-4.50 (4,600) 3.75 (23,975) (81,525) .25-4.50 (81,525)
Balance outstanding, December Granted Exercised Expired	73,187 6.00 73,187 (6,000) 1.50-2.50 (41,200) 2.50-5.20 (47,200) (47,850) 1.50-4.50 (47,850)
	Der 31, 1995 800,287 .25-6.00 260,338 2.00-5.20 1,060,625 140,600 7.00-8.50 140,600 (6,500) 6.00-7.00 (21,668) 5.20 (28,168) 0,1996
Balance outstanding, June 30 (unaudited)	934,387 .25-8.50 226,670 2.00-5.00 1,161,057
Exercisable at June 30, 1996	(unaudited) 359,500 .25-1.65 359,500 262,200 2.50-4.50 206,670 2.00-2.50 468,870 31,984 6.00 20,000 5.00 51,984
Total exercisable at June 30, (unaudited)	
Proceeds of exercisable at Ju-	

  |F-15

Stock Split

On August 8, 1996 the Board of Directors approved a 1-for-2 reverse stock split and an increase in authorized common shares to 20,000,000, and authorized 1,000,000 shares of preferred stock (par value \$.01), which were approved by the stockholders on September 10, 1996. The stock split has been retroactively reflected in the accompanying financial statements and notes for all periods presented.

# STOCK PURCHASE AGREEMENT (UNAUDITED)

On April 26, 1996, the Company entered into a Stock Purchase Agreement and Exclusive Distributor Agreement for five years with a foreign distributor. Pursuant to the Stock Purchase Agreement, the Company issued 117,647 shares of redeemable common stock at a price per share of \$8.50, for which it received net proceeds of \$898,503. Issuance costs were \$101,497. Furthermore, the agreement may require the Company to repurchase the stock at the issuance price (\$1,000,000 in total) in three equal installments in the event that the Distribution Agreement is terminated by the Company prior to the completion of a public offering. Completion of a public offering will terminate the redemption feature and cause the reclassification of these shares into stockholders' equity. In addition, the distributor is restricted from selling these securities for a one-year period after completion of such Offering. The Company utilized the 80,000 shares of Treasury Stock in connection with this transaction.

BioSeq, Inc. (Unaudited)

In October 1996, the Company entered into a License Agreement, Purchase Agreement, Stockholders' Agreement and Warrant Agreement with BioSeq, a privately held, technology based development stage company.

The Company has agreed to purchase convertible preferred stock of BioSeq for an aggregate of \$1,482,500 in three installments. Of the \$1,482,500, \$210,000 was invested at the date of the agreements and \$522,500 is required to be invested within ten business days of the closing of the initial public offering of the Company's common stock provided the closing occurs before December 31, 1996. The Company must make the remaining \$750,000 installment if BioSeq attains certain technical milestones by July 31, 1997. If such milestones are not attained by BioSeq by July 31, 1997, the Company will still have the option to make the remaining \$750,000 investment until December 31, 1997. Under the operative documents, the Company has price anti-dilution protection, pre-emptive rights and the right to board representation, the last of which terminates if the Company fails to make the second installment under the Purchase Agreement. In addition, the Company was granted warrants to acquire additional shares of common stock of BioSeq for additional consideration under certain conditions, provided that this right is not exercisable to the extent it would cause the Company's ownership to equal or exceed 20%. The Company is accounting for its investment in BioSeq on the cost basis in accordance with the provisions of APB 18 since the cumulative investment is and must remain less than 20% of the equity of BioSeq and the Company does not exert significant influence or control. Due to the uncertainty of technology based development stage enterprises and in accordance with the provisions of SFAS 121, the Company will perform a periodic analysis of the investment to determine whether the carrying value of its investment in BioSeq has been impaired. If so determined, the Company would adjust the carrying value of its investment by taking a charge to earnings.

Upon the earlier of payment of the final installment of the Company's aggregate \$1,482,500 investment and December 31, 1997, the Company will be granted a worldwide right to use the BioSeq technology relating to sequencing and analysis services. The License will be exclusive until BioSeq commences selling on a commercial basis the equipment used in the DNA sequencing and analysis process, at which time the License will become non-exclusive. The License provides that the Company will pay BioSeq royalties ranging from five percent to ten percent of net revenues arising out of the services performed by the Company with the licensed technology. The Company will account for the royalty as a cost of revenue as the revenues are earned.

# BOSTON BIOMEDICA, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED) (INFORMATION AS OF JUNE 30, 1996 AND FOR THE SIX MONTHS ENDED JUNE 30, 1996 AND 1995 IS UNAUDITED.)

# (11) SUBSEQUENT EVENTS -- (CONTINUED)

Initial Public Offering (Unaudited)

The Company has filed a registration statement for the sale of shares of common stock. Accordingly, the unaudited pro forma balance sheet has been prepared assuming the reclassification of the redeemable common stock into common stock as of June 30, 1996. There can be no assurances that the initial public offering of common stock will be successfully completed.

## (12) SUPPLEMENTARY PRO FORMA EARNINGS PER SHARE -- (UNAUDITED)

If the Offering had been completed on January 1, 1995, a portion of the proceeds would have been used to retire all debt outstanding at that time, and all debt incurred in 1995 and 1996 would not have been needed. Based on the foregoing, supplemental pro forma net earnings per share of common stock would have been \$.09 and \$.06 for the year ended December 31, 1995 and the six months ended June 30, 1996, respectively. Such net earnings per share of common stock are based on 3,600,007 and 3,701,173 shares of common stock respectively, consisting of 3,151,477 and 3,252,643 shares of common stock and common stock equivalents plus 448,530 shares assumed to be issued at \$9.00 per share as if the Offering had occurred on January 1, 1995 to retire indebtedness outstanding during 1995.

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# **GLOSSARY**

**AIDS** 

Acquired Immune Deficiency Syndrome. AIDS is caused by infection with the Human

Immunodeficiency Virus, HIV.

Antibodies Binding proteins naturally produced by the body in

response to exposure to non-self agents (e.g., bacteria, viruses, cancer cells). Antibodies form part of the immunological defense system.

Antigens Foreign non-self agents (such as the proteins or

the nucleic acids of infectious agents) that stimulate an immune response, including the

production of antibodies.

Assay Synonym for test: qualitative or quantitative

measurement of some component of a material.

Chlamydia A sexually transmitted pathogen that can cause

Trachoma (an eye disease which culminates in blindness), chronic infection of genitals (which can result in infertility), and pneumonia,

especially in the newborn.

CLIA The Clinical Laboratory Improvement Amendments,

passed by Congress in October 1988, and formulated into regulations and implemented by the Health Care Financing Administration beginning in 1992. CLIA refers to a set of regulations which govern the staffing and function of all U.S. laboratories

that perform in vitro diagnostic tests for clinical use, except for blood bank laboratories and Veterans' Administration hospital laboratories, which are regulated separately using similar rules.

Cytomegalovirus

A virus responsible for several diseases that are especially prevalent in immunocompromised patients such as those infected with HIV, receiving organ transplants or receiving cancer chemotherapy.

Diagnostic Components

onents The solutions and materials that are combined, sometimes after further manufacture, to make an in vitro diagnostic test kit.

DNA

Deoxyribonucleic Acid, together with RNA, a class of molecules called "nucleic acids." DNA carries the genetic information in most living organisms. The DNA of each cell contains the information for "building" a whole organism (e.g., a virus, a plant, or a whole human being). DNA testing can identify microscopic amounts of the genetic material of a virus or bacterium, thus indicating its presence in quantities undetectable in the bloodstream by immunoassay techniques.

**ELISA** 

Enzyme-Linked Immunosorbent Assay, a biochemical procedure in which interactions among antibodies, antigens and enzymes are used to detect and quantify various diseases and other materials of interest through the measurement of color released at the end of the assay.

End-User

The purchaser and consumer of an in vitro diagnostic test kit; usually clinical laboratories, but may also be other health care providers or members of the general public.

G-1

Hepatitis

A disease that causes inflammation of and damage to the liver, often caused by a virus. In advanced stages, hepatitis can result in life threatening liver dysfunction, liver cirrhosis or liver cancer. The most common causes of viral hepatitis are the Hepatitis A, B and C viruses (HAV, HBV and HCV).

HIV

Human Immunodeficiency Virus. HIV, a retrovirus, causes AIDS. HIV infection leads to the destruction of the immune system.

Immunology

Narrowly defined as the study of the immune system, but often used to describe tests for infectious diseases which rely on the principle of the binding of antigens and antibodies.

Immunoassay

A test that relies on the specificity of the reaction between antibodies and antigens to detect and measure the concentration of biological molecules.

In Vitro

Laboratory procedures that occur "in the test tube," or outside the body. In vitro diagnostic testing is the process of analyzing blood, urine, saliva and other specimens outside the body to screen for, monitor or diagnose diseases and other medical conditions.

Infectious Agent

Any microorganism, such as bacteria, viruses,

fungi or other parasites, capable of invading another organism, with or without pathological manifestations.

Levey-Jennings Chart

hart A chart on which the test results for a Run Control are plotted over time, so that the reproducibility of a test method can be monitored. The acceptable range for the Run Control, as determined by each individual test kit end-user, is also indicated on the chart.

Lyme Disease

A bacterial infection caused by a spirochete called Borrelia burgdorferi (B. burgdorferi). This spirochete usually infects the deer tick which then bites a person or animal, thus transmitting the infection.

Marker

A substance which, when detected in blood or other study sample by an in vitro diagnostic test, is indicative of the presence of disease or other medical condition.

Microbiology

The clinical laboratory testing segment that specializes in the detection of organisms that cause infectious disease. Often used to refer to traditional tests that use a growth medium which enables an organism, if present, to replicate and be detected visually. Newer methods for detection and monitoring of infectious diseases such as immunology and molecular biology methods are sometimes performed in separate laboratories and sometimes incorporated into microbiology laboratories.

Molecular Biology

The clinical laboratory testing segment which uses newer methods such as PCR to detect nucleic acids (i.e., DNA and RNA) for infectious disease diagnosis and other purposes.

G-2

Multi-Marker Run Control A run control designed to be used with several tests for different analytes or markers. These controls are designed to cover groups of markers that are tested in the same laboratory section, e.g., Accurun 1(R) is a multi-marker run control

for blood bank tests.

Nucleic Acids

Two families of compounds called deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) that carry the coded information from which all living organisms are made.

Pathogen

An organism that causes disease in the study subjects (e.g., a virus which causes disease in humans is human pathogen; an insect that causes disease in a plant is a plant pathogen).

PCR

Polymerase Chain Reaction, a sequence of chemical steps using DNA primers (short pieces of nucleic acids) to locate and copy (amplify) specific sequences of DNA, if present, to a concentration high enough for chemical detection.

Performance Panels

ls A set of serum and plasma samples collected from many different individuals and characterized for the presence or absence of a particular disease marker.

Plasma

The clear liquid portion of blood which contains

clotting factors, proteins, antibodies, hormones, electrolytes and other components dissolved in water. Plasma differs from serum only in that plasma contains clotting factors in addition to its other components, and serum does not.

Qualification Panels

els Dilutions of human plasma or serum manifesting a full range of reactivities in test kits for a specific marker.

**Qualitative Test** 

An assay for which the reportable results are positive, negative or indeterminate. An alternative set of terms sometimes used to express qualitative test results is reactive, non-reactive or gray zone.

**Quality Control Products** 

roducts Materials including characterized samples of various kinds, data sheets and software, all designed for use in the performance evaluation of in vitro diagnostic tests during their development, manufacture or use.

**Quantitative Test** 

An assay for which the reportable results are numeric.

Reactivity

Test result for a qualitative test; can take one of three forms: positive, negative or indeterminate.

Reagent

A substance, usually a chemical solution, used as a component of an in vitro diagnostic test.

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Retrovirus

A virus with its genetic information encoded in RNA rather than DNA. HIV is a retrovirus.

RNA

Ribonucleic acid, with DNA, a class of molecules called nucleic acids. RNA functions with DNA in most organisms to translate the coded genetic information into the organism itself. In some viruses, RNA substitutes for DNA in carrying the coded information from which the organism is made. HIV and HCV are RNA viruses.

Run Controls

Well-characterized samples designed to resemble the donor and patient samples routinely tested with a given method, manufactured to specific levels of reactivity and provided in quantities sufficient to be used each time the test is run, over a period of time, so that test performance can be continuously monitored.

Sensitivity

The ability of a test to detect accurately small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance the test can detect, and the fewer false negatives will be reported. Sensitivity and specificity are two important measures of the quality of a test.

Sensitivity Panels

Precise dilutions of human plasma or serum containing a known amount of an infectious disease marker as calibrated against international standards.

Seroconversion Panels Plasma samples collected from a single individual over a specific time period showing conversion from negative to positive for markers of an

infectious disease.

Serum

The clear liquid portion of blood which contains proteins, antibodies, hormones, electrolytes and other components dissolved in water. Serum differs from plasma only in that serum does not contain clotting factors.

Single Analyte Run Control A run control designed to be used with tests for a single analyte or marker, e.g., Accurun 106 is a positive control for HIV antigen tests from several manufacturers.

Specificity

The ability of a test to distinguish between similar materials. The greater the specificity, the better a test is at identifying a substance in the presence of substances of similar makeup, and the fewer false positives will be reported. Sensitivity and specificity are two important measures of the quality of a test.

Therapeutic Index

A mathematical description of the potential usefulness of a candidate drug, based on its toxicity to the host system versus its effectiveness against the pathogen. The Therapeutic Index of a candidate drug is compared to the Therapeutic Index in the same test system of a drug already in use for the disease being studied.

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Titer

An approximation of the quantity of a marker in a qualitative test, arrived at by diluting the sample repeatedly and testing the dilutions until the marker is no longer detected by the test method.

Toxoplasma

A protozoan parasite, ubiquitous in the environment, and which causes Toxoplasmosis. Toxoplasmosis is commonly acquired by eating food contaminated by cysts. Pregnant women may be at risk of acquiring Toxoplasmosis from cats, with subsequent infection of the baby.

Virus

A microorganism dependent on host cells in order to grow and reproduce.

Western Blot Method

The standard diagnostic method for confirmation of the presence of an infectious disease marker (e.g. HIV, Borrelia burgdorferi), in which lysate (a mixture of proteins) is separated on a gel by electrochemical means and then transferred to a nitrocellulose filter. The filter is then tested against a blood sample to identify antibodies to the proteins.

Photograph showing certain of the Company's Quality Control Panel Products, including Seroconversion and Performance Panels.

NO DEALER, SALESMAN OR ANY OTHER PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR MAKE ANY REPRESENTATIONS OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS IN CONNECTION WITH THE OFFERING DESCRIBED HEREIN, AND, IF GIVEN OR MADE, SUCH OTHER INFORMATION OR REPRESENTATIONS MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY, OR THE UNDERWRITERS. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL, UNDER ANY CIRCUMSTANCES, CREATE ANY IMPLICATION THAT THE INFORMATION CONTAINED HEREIN IS CORRECT AS OF ANY TIME SUBSEQUENT TO ITS DATE. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OTHER THAN THOSE SPECIFICALLY OFFERED HEREBY OR OF ANY SECURITIES OFFERED HEREBY IN ANY JURISDICTION TO ANY PERSON TO WHOM IT IS UNLAWFUL TO MAKE AN OFFER OR SOLICITATION IN SUCH JURISDICTION. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY SUCH SECURITIES IN ANY CIRCUMSTANCES IN WHICH SUCH OFFER OR SOLICITATION IS UNLAWFUL.

#### -----

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UNTIL , 1996 (25 DAYS AFTER THE DATE OF THIS PROSPECTUS) ALL DEALERS EFFECTING TRANSACTIONS IN THE SHARES OF COMMON STOCK, WHETHER OR NOT PARTICIPATING IN THIS DISTRIBUTION, MAY BE REQUIRED TO DELIVER A PROSPECTUS. THIS IS IN ADDITION TO THE OBLIGATIONS OF DEALERS TO DELIVER A PROSPECTUS WHEN ACTING AS UNDERWRITERS AND WITH RESPECT TO THEIR UNSOLD ALLOTMENTS OR SUBSCRIPTIONS.

\_\_\_\_\_

1,600,000 SHARES

[LOGO]

BOSTON BIOMEDICA, INC.

COMMON STOCK

PROSPECTUS

OSCAR GRUSS & SON INCORPORATED

KAUFMAN BROS., L.P.

, 1996

# PART II INFORMATION NOT REQUIRED IN PROSPECTUS

# ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

TOTAL EXPENSES

-----

SEC Registration Fee \$8,508

NASD Filing Fee 2,708

Nasdaq National Market Listing Fee 30,000\*

Blue Sky Fees and Expenses 15,000\*

Underwriters' Non-Accountable Expense
Allowance 144,000\*

Transfer Agent and Registrar Fees 2,500\*

Transfer Agent and Registrar Fees
Accounting Fees and Expenses
Legal Fees and Expenses
Printing and Engraving
Miscellaneous

2,500\*
150,000\*
150,000\*
160,000\*
79,284\*

TOTAL \$792,000\*

- -----

\* Estimate

#### ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

The Company's Amended and Restated By-Laws include provisions to permit the indemnification of officers and directors of the Company for damages arising out of the performance of their duties unless such damages arise out of the officer's or director's failure to exercise his duties and to discharge the duties of his office in good faith and in the reasonable belief that his action was in, or not opposed to, the best interest of the Company, and with respect to any criminal action or proceeding, had no reasonable cause to believe that his conduct was unlawful. The Company intends to enter into indemnification contracts with each of its directors and officers. Reference is hereby made to the caption "Management -- Limitation of Officers' and Directors' Liability; Indemnification Agreements."

Reference is hereby made to the caption "Description of Capital Stock -- Limitation of Directors' Liability" in the Prospectus, which is a part of this Registration Statement.

Reference is hereby made to Section 6 of the Underwriting Agreement between the Company and the Underwriter, filed as Exhibit 1.1 to this Registration Statement, for a description of indemnification arrangements between the Company and the Underwriter.

## ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

The following information is furnished with regard to all securities issued by the Registrant within the past three years which were not registered under the Securities Act.

In August 1996, the stockholders of the Registrant voted to approve an amendment to the Registrant's Articles of Organization to effect a one-for-two reverse stock split of the Registrant's Common Stock, \$.01 par value per share. All references to number of shares of Common Stock give effect to this stock split.

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- (1) In August 1993, the Registrant sold to eight individual investors an aggregate of 45,000 shares of Common Stock for total cash consideration of \$202,500, at a price per share of \$4.50, and to another investor 1,958 shares of Common Stock in exchange for services rendered valued at \$8,811, which securities were not registered under the Securities Act.
- (2) In April 1994, the Registrant sold to eight individual investors an aggregate of 21,200 shares of Common Stock, for total consideration of \$127,200 at a price per share of \$6.00, which securities were not registered under the Securities Act.
- (3) From June through December 1994, the Registrant sold the following at \$6.00 per share: to one investor 5,000 shares of Common Stock for cash consideration of \$30,000, to a second investor 1,167 shares of Common Stock for cash consideration of \$3,501 and in exchange for services rendered valued at \$3,501, and to a third investor 2,494 shares in exchange for services rendered valued at \$14,964, which securities were not registered under the Securities Act.
- (4) In November and December 1995, the Registrant sold to two investors an aggregate of 7,800 shares of Common Stock for total cash consideration of \$54,600 at a price of \$7.00, and to another investor 734 shares of Common Stock in exchange for services rendered valued at \$5,138, which securities were not registered under the Securities Act.

- (5) On April 26, 1996, the Registrant sold 117,647 shares of Common Stock to Kyowa Medex, Co., Ltd. for total cash consideration of \$1,000,000, which securities were not registered under the Securities Act.
- (6) For the period August 1, 1993 to date, the Registrant granted to directors, officers, employees and consultants, 15,000 (\$6.00 per share), 63,000 (\$4.50 to \$7.00 per share), 244,037 (\$4.50 to \$8.50 per share), and 8,000 (\$6.00 per share), respectively, options to purchase shares of Common Stock under the Registrant's 1987 Non-Qualified Stock Option Plan or Employee Stock Option Plan, which securities were not registered under the Securities Act.
- (7) During the period from March 1994 through June 1996, the Registrant issued an aggregate of 88,993 shares to fifteen persons pursuant to the exercise of options, warrants or convertible notes of the Registrant for exercise prices ranging from \$0.25 to \$5.20 per share (an aggregate exercise price of \$219,977.50), which securities were not registered under the Securities Act.

To the extent that the foregoing transactions constituted "sales" within the meaning of the Securities Act, the securities issued in such transactions were not registered under the Securities Act, as amended, in reliance upon the exemptions from registration set forth in Section 3(b) and 4(2) of the Securities Act, relating to sales by an issuer not involving any public offering, or in reliance upon Regulation S of the Securities Act relating to sales by an issuer of securities outside the United States. None of the foregoing transactions, either individually or in the aggregate, involved a public offering.

## ITEM 16. FINANCIAL STATEMENT SCHEDULE AND EXHIBITS

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<TABLE>
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  <S>
           <C>
  II
         -- Valuation and Qualifying Accounts
</TABLE>
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<CAPTION>
 EXHIBIT
  NO.
 <S>
           <C>
          -- Form of Underwriting Agreement
  1.1
          -- Amended and Restated Articles of Organization of the Registrant*
  3.1
          -- Amended and Restated By-Laws of the Registrant*
  3.2
          -- Description of Certificate for Shares of the Registrant's Common Stock*
  4.1
</TABLE>
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<TABLE>
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EXHIBIT
NO.
--<S> <C>

- 5.1 -- Legal Opinion of Brown, Rudnick, Freed & Gesmer
- 10.1 -- Agreement, dated January 17, 1994, between Roche Molecular Systems, Inc. and the Registrant\*

- 10.2 -- Exclusive License Agreement, dated December 6, 1994, between the University of North Carolina at Chapel Hill and the Registrant\*\* 10.3 -- Contract, dated September 30, 1995, between the National Institutes of Health and the Registrant (No. 1-AI-55273) 10.4 -- Contract, dated September 30, 1995, between the National Institutes of Health and the Registrant (No. 1-AI-55277) -- Contract, dated March 1, 1993, between the National Cancer Institute and the 10.5 10.6 -- Agreement, dated October 1, 1995, between Ajinomoto Co., Inc. and the Registrant\*\*\* -- Lease Agreement, dated June 30, 1992, for Rockville, Maryland Facility between 10.7 Cambridge Biotech Corporation and the Registrant 10.8 -- Lease Agreement, dated July 28, 1995, for New Britain, Connecticut Facility between MB Associates and the Registrant 10.9 -- Worcester County Institution for Savings Warrant dated December 1, 1995 (No. 1)\* 10.10 -- Worcester County Institution for Savings Warrant dated July 26, 1993 (No. 2)\* -- Stock Purchase Agreement, dated June 5, 1990, between G&G Diagnostics Limited 10.11Partnership I and the Registrant, as amended\* 10.12 -- Purchase and Sale Agreement, dated December 11, 1995, for 375 West Street Property between James Leonard, Trustee, C.W.B. Trust and the Registrant\* 10.13 -- Purchase and Sale Agreement, dated December 20, 1995, for 80 Manley Street Property between the Registrant and Donald M. Leonard, Trustee, Live Oak Realty Trust\* -- Stock Purchase Agreement, dated April 26, 1996, between Kyowa Medex Co., Ltd. 10.14 and the Registrant\* 10.15 -- 1987 Non-Qualified Stock Option Plan\* 10.16 -- Employee Stock Option Plan\* 10.17 -- Form of Underwriters Warrant (contained in Exhibit 1.1) 10.18.1 -- Second Amended and Restated Loan and Security Agreement, dated August 2, 1995, between the First National Bank of Boston and the Registrant, as amended\* 10.18.2 -- Note Payable to The First National Bank of Boston, dated October 1994, in the amount of \$200,000\* 10.18.3 -- Note Payable to The First National Bank of Boston, dated October 1994, in the amount of \$849,000\* 10.18.4 -- Note Payable to The First National Bank of Boston, dated August 1995, in the amount of \$350,000\*
- 10.18.5 -- Note Payable to The First National Bank of Boston, dated December 1995, in the amount of \$100,000\*
- 10.18.6 -- Mortgage Note to The First National Bank of Boston, dated December 1995, in the amount of \$750,000\*
- -- Note Payable to The First National Bank of Boston, dated July 1996, in the amount 10.18.7
- 10.19 -- Form of Indemnification Agreement with Officers and Directors\*

</TABLE>

<TABLE>

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<CAPTION> **EXHIBIT** NO. <C> <S>10.20

-- Purchase Agreement, dated October 7, 1996, between BioSeq, Inc. and the Registrant\* 10.21 -- Warrant Agreement, dated October 7, 1996, between BioSeq, Inc. and the Registrant\*

10.22 -- Stockholders' Agreement, dated October 7, 1996, between BioSeq, Inc. and the Registrant\* 10.23 -- License Agreement, dated October 7, 1996, between BioSeq, Inc. and the Registrant\*

11 -- Statement re Computation of Per Share Earnings\*

21 -- Subsidiaries of the Registrant\*

-- Consent of Brown, Rudnick, Freed & Gesmer (contained in Exhibit 5.1) 23.1

23.2 -- Consent of Coopers & Lybrand L.L.P., independent accountants

24 -- Power of Attorney\* 27 -- Financial Data Schedule\*

</TABLE>

Previously filed.

<sup>\*\*</sup> Confidential Treatment requested for certain portions of this document which

#### ITEM 17. UNDERTAKINGS

- (a) The undersigned Registrant hereby undertakes:
- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement;
- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;
- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the Offering.
- (b) The undersigned Registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- (c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the Registrant's By-Laws, the Underwriting Agreement relating to this Offering, or otherwise, the Registrant has been

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advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of

such issue.

- (d) The undersigned Registrant hereby further undertakes that:
- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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# **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Amendment No. 2 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of West Bridgewater, Commonwealth of Massachusetts, on October 25, 1996.

BOSTON BIOMEDICA, INC.

By: /s/ RICHARD T. SCHUMACHER

RICHARD T. SCHUMACHER PRESIDENT

PURSUANT TO THE REQUIREMENTS OF THE SECURITIES ACT OF 1933, THIS AMENDMENT NO. 2 TO THE REGISTRATION STATEMENT HAS BEEN SIGNED BY THE FOLLOWING PERSONS IN THE CAPACITIES AND ON THE DATES INDICATED.

CAPTIO						
	SIGNATURE		TITLE		DATE	
	CHARD T. SCHU CHARD T. SCHUI	and Direct	_	<c> al Executiv</c>	ve Officer	October 25, 1996
	EVIN W. QUINLA  VIN W. QUINLA	Officer and		ancial and	Accounting	October 25, 1996
	*	Director		October 2:	5, 1996	
	 NRY A. MALKAS	SIAN				

\* Director October 25, 1996

FRANCIS E. CAPITANIO

\* Director October 25, 1996

CALVIN A. SARAVIS

\*By /s/ RICHARD T. SCHUMACHER
----RICHARD T. SCHUMACHER

RICHARD T. SCHUMACHER ATTORNEY-IN-FACT

</TABLE>

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#### REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Stockholders of BOSTON BIOMEDICA, INC.:

In connection with our audits of the consolidated financial statements of Boston Biomedica, Inc. and Subsidiaries, as of December 31, 1994 and 1995, and for each of the three years in the period ended December 31, 1995, which financial statements are included in this Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-10759), we have also audited the consolidated financial statement schedule listed in Item 16 herein.

In our opinion, this consolidated financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information required to be included therein.

COOPERS & LYBRAND L.L.P.

Boston, Massachusetts March 12, 1996

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SCHEDULE II

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES VALUATION AND QUALIFYING ACCOUNTS

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RECOVERIES

BALANCE AT FOR ACCOUNTS UNCOLLECTIBLE BALANCE AT BEGINNING PROVISION FOR PREVIOUSLY ACCOUNTS END OF ALLOWANCE FOR DOUBTFUL ACCOUNTS OF PERIOD BAD DEBT WRITTEN OFF WRITTEN OFF PERIOD

Six months ended June 30, 1996 \$142,372 \$ 77,145 \$ (85,938) \$133,579 94,723 181,084 (133,435)1995 142,372 1994 102,099 43,956 94,723 (51,332)1993 22,956 21,000 43,956 </TABLE>

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#### INDEX TO EXHIBITS

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NUMBER	DESCRIPTION	PAGE
EXHIBIT		NUMBERED
		SEQUENTIALLY

- 1.1 -- Form of Underwriting Agreement
- 3.1 -- Amended and Restated Articles of Organization of the Registrant\*
- 3.2 -- Amended and Restated By-Laws of the Registrant\*
- 4.1 -- Description of Certificate for Shares of the Registrant's Common Stock\*
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   Diagnostics Limited Partnership I and the Registrant, as amended\*
- 10.12 -- Purchase and Sale Agreement, dated December 11, 1995, for 375 West Street Property between James Leonard, Trustee, C.W.B. Trust and the Registrant\*
- 10.13 -- Purchase and Sale Agreement, dated December 20, 1995, for 80 Manley Street Property between the Registrant and Donald M. Leonard, Trustee, Live Oak Realty Trust\*
- 10.14 -- Stock Purchase Agreement, dated April 26, 1996, between Kyowa Medex Co., Ltd. and the Registrant\*
- 10.15 -- 1987 Non-Qualified Stock Option Plan\*
- 10.16 -- Employee Stock Option Plan\*
- 10.17 -- Form of Underwriters Warrant (contained in Exhibit 1.1)
- 10.18.1 -- Second Amended and Restated Loan and Security Agreement, dated August 2, 1995, between the First National Bank of Boston and the Registrant, as amended\*
- 10.18.2 -- Note Payable to The First National Bank of Boston, dated October 1994, in the amount of \$200,000\*
- 10.18.3 -- Note Payable to The First National Bank of Boston, dated October 1994, in the amount of \$849,000\*

</TABLE>

# INDEX TO EXHIBITS (CONTINUED)

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EXHIB	IT.	NUMBERED				
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10.18.4	4 Note Payable to The First National Bank of Boston, dated August 1995, in the amount of \$350,000*					
10.18.5						
	the amount of \$100,000*					
10.18.6	Mortgage Note to The First National Bank of Boston, dated December 1995, in					
	the amount of \$750,000*					
10.18.7	Note Payable to The First National Bank	of Boston, dated July 1996, in the				
10.10	amount of \$250,000*					
10.19	Form of Indemnification Agreement with Officers and Directors*					
10.20	Purchase Agreement, dated October 7, 1996, between BioSeq, Inc. and the Registrant*					
10.21 10.22	Warrant Agreement, dated October 7, 1996, between BioSeq, Inc. and the Registrant*					
10.22						
10.23	Registrant*	hatwaan DioCag Ing and the Dagistront*				
10.23	License Agreement, dated October 7, 1996, between BioSeq, Inc. and the Registrant* Statement re Computation of Per Share Earnings*					
21	Subsidiaries of the Registrant*					
23.1	Consent of Brown, Rudnick, Freed & Gesmer (contained in Exhibit 5.1)					
23.2	Consent of Coopers & Lybrand L.L.P., independent accountants					
24	Power of Attorney*					
27	Financial Data Schedule*					

<sup>\*</sup> Previously filed.

<sup>\*\*</sup> Confidential Treatment requested for certain portions of this document which has been previously filed.

<sup>\*\*\*</sup> Confidential Treatment requested for certain portions of this document.

1,600,000 Shares\*

Boston Biomedica, Inc.

Common Stock

#### UNDERWRITING AGREEMENT

\_\_\_\_, 1996

OSCAR GRUSS & SON INCORPORATED KAUFMAN BROS., L.P. c/o Oscar Gruss & Son Incorporated 74 Broad Street New York, New York 10004

Ladies and Gentlemen:

Boston Biomedica, Inc., a Massachusetts corporation (the "COMPANY"), proposes to issue and sell 1,600,000 shares (the "FIRM SHARES") of Common Stock of the Company, \$.01 par value (the "COMMON STOCK"), to you (the "UNDERWRITERS") as set forth on Schedule I hereto. In addition, the Company has agreed to grant to you an option (the "OPTION") to purchase up to an additional 240,000 shares of Common Stock (the "OPTION SHARES") on the terms and for the purposes set forth in Section 1(b) below. The Firm Shares and the Option Shares are referred to collectively herein as the "SHARES."

It is understood that, subject to the conditions hereinafter stated, the Firm Shares will be sold to you. The Company confirms its agreement with the Underwriters as follows:

\* Plus an option to purchase up to an additional 240,000 shares to cover over-

#### 1. AGREEMENT TO SELL AND PURCHASE

a. On the basis of the representations, warranties and agreements herein contained and subject to all the terms and conditions of this Agreement, (i) the Company agrees to issue and sell the Firm Shares to the several Underwriters and (ii) each of the Underwriters, severally and not jointly, agrees to purchase from the Company the respective number of Firm Shares set forth opposite that Underwriter's name in Schedule I hereto, at the purchase price of \$ for each Firm Share.

b. Subject to all the terms and conditions of this Agreement, the Company grants the Option to the several Underwriters to purchase, severally and not jointly, up to the maximum number of Option Shares at the same price per share as the Underwriters shall pay for the Firm Shares. The Option may be exercised only to cover over-allotments in the sale of the Firm Shares by the Underwriters and may be exercised in whole or in part at any time (but not more than once) on or before the 30th day after the date of this Agreement upon written or telegraphic notice (the "OPTION SHARES NOTICE") by the Underwriters to the Company no later than 12:00 noon, New York City time, at least two and no more than three business days before the date specified for closing in the Option Shares Notice (the "OPTION CLOSING DATE"), setting forth the aggregate number of Option Shares to be purchased and the time and date for such purchase. On the Option Closing Date, the Company will sell to the Underwriters the number of Option Shares set forth in the Option Shares Notice, and each Underwriter will purchase such percentage of the Option Shares as is equal to the percentage

of the Firm Shares that such Underwriter is purchasing, as adjusted by the Underwriters in such manner as they deem advisable to avoid fractional shares.

c. Subject to the terms and conditions herein set forth, on the Closing

Date (as defined below), the Company shall issue to Oscar Gruss & Son

Incorporated ("OSCAR GRUSS") and Kaufman Bros., L.P., in their individual
capacity, warrants in the form attached hereto as Exhibit A (the

"REPRESENTATIVES' WARRANTS") to purchase \_\_\_\_\_\_ and \_\_\_\_\_ shares of
Common Stock, respectively [an aggregate of 160,000 shares], at an exercise
price equal to 135% of the price per Firm Share.

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#### 2. DELIVERY AND PAYMENT

Delivery of the Firm Shares shall be made to the Underwriters against payment of the purchase price by certified or official bank check payable in New York Clearing House (next-day) funds to the order of the Company at the offices of Fulbright & Jaworski L.L.P., 666 Fifth Avenue, New York, New York 10103, at 10:00 a.m., New York Time, on the third (or, if the Firm Shares are priced, as contemplated by Rule 15c6-1(c) under the Securities Exchange Act of 1934, as amended (the "EXCHANGE ACT"), after 4:30 p.m. New York Time, the fourth) full business day following the commencement of the offering contemplated by this Agreement, or at such time on such other date, not later than five business days after the date of this Agreement, as may be agreed upon by the Company and the Underwriters (such date is hereinafter referred to as the "CLOSING DATE").

To the extent the Option is exercised, delivery of the Option Shares against payment by the Underwriters (in the manner specified above) will take place at the offices specified above for the Closing Date at the time and date (which may be the Closing Date) specified in the Option Shares Notice.

Certificates evidencing the Shares shall be in definitive form and shall be registered in such names and in such denominations as the Underwriters shall request at least two business days prior to the Closing Date or the Option Closing Date, as the case may be, by written notice to the Company. For the purpose of expediting the checking and packaging of certificates for the Shares, the Company agrees to make such certificates available for inspection at least 24 hours prior to the Closing Date or the Option Closing Date, as the case may be.

The cost of original issue tax stamps, if any, in connection with the issuance and delivery of the Shares by the Company to the respective Underwriters shall be borne by the Company. The Company will pay and save each Underwriter and any subsequent holder of the Shares harmless from any and all liabilities with respect to or resulting from any failure or delay in paying federal and state stamp and other transfer taxes, if any, which may be payable or determined to be payable in connection with the original issuance or the sale to such Underwriter of the Shares sold by such entity.

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# 3. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents, warrants and covenants to each Underwriter that:

a. A registration statement (Registration No. 333-10759) on Form S-1 relating to the Shares, including a preliminary prospectus and such amendments to such registration statement as may have been required to the date of this Agreement, has been prepared by the Company under the provisions of the Securities Act of 1933, as amended (the "ACT"), and the rules and regulations (collectively referred to as the "RULES AND REGULATIONS") of the Securities and Exchange Commission (the "COMMISSION") thereunder, and has been filed with the

Commission. The term "preliminary prospectus" as used herein means a preliminary prospectus as contemplated by Rule 430 or Rule 430A of the Rules and Regulations included at any time as part of the registration statement. Copies of such registration statement, amendments and exhibits thereto and of each related preliminary prospectus have been delivered to the Representatives. If such registration statement has not become effective, a further amendment to such registration statement, including a form of final prospectus, necessary to permit such registration statement to become effective will be filed promptly by the Company with the Commission. If the registration statement has become effective, a final prospectus containing information permitted to be omitted at the time of effectiveness by Rule 430A of the Rules and Regulations will be filed promptly by the Company with the Commission in accordance with Rule 424(b) of the Rules and Regulations. The term "REGISTRATION STATEMENT" means the registration statement as amended at the time it becomes or became effective (the "EFFECTIVE DATE"), including financial statements and all exhibits and any information deemed to be included by Rule 430A. If an abbreviated registration statement is prepared and filed with the Commission in accordance with Rule 462(b) under the Act (an "ABBREVIATED REGISTRATION STATEMENT"), the term "Registration Statement" as used in this Agreement includes the Abbreviated Registration Statement. The term "PROSPECTUS" means (i) if the Company relies on Rule 434 of the Rules and Regulations, the Term Sheet that is first filed pursuant to Rule 424(b)(7) under the Act, together with the preliminary prospectus identified therein that such Term Sheet supplements, (ii) if the Company does not rely on Rule 434 of the Rules and Regulations, the prospectus first filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations; or (iii) if the Company does not rely on Rule 434 of the Rules and Regulations and if no prospectus is required to be filed pursuant to Rule 424(b) of the Rules and Regulations, the prospectus

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included in the Registration Statement. The term "TERM SHEET" means any term sheet that satisfies the requirements of Rule 434 of the Rules and Regulations.

b. The Commission has not issued any order preventing or suspending the use of any Preliminary Prospectus. When any Preliminary Prospectus was filed with the Commission it complied in all material respects with the applicable requirements of the Act and the Rules and Regulations and did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. On the Effective Date, the date the Term Sheet, if utilized, is first filed with the Commission pursuant to Rule 424(b), the date the Prospectus is first filed with the Commission pursuant to Rule 424(b) (if required), at all times subsequent to and including the Closing Date and, if later, the Option Closing Date and when any post-effective amendment to the Registration Statement becomes effective or any amendment or supplement to the Prospectus is filed with the Commission, the Registration Statement and the Prospectus (as amended or as supplemented if the Company shall have filed with the Commission any amendment or supplement thereto), including the financial statements included in the Prospectus, did and will comply with all applicable provisions of the Act and the Rules and Regulations and will contain all statements required to be stated therein in accordance with the Act and the Rules and Regulations. At the Effective Date and when any post-effective amendment to the Registration Statement becomes effective, no part of the Registration Statement, the Prospectus or any such amendment or supplement did or will contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading. At the Effective Date, the date the Term Sheet, the Prospectus or any amendment or supplement to the Prospectus is filed with the Commission and at the Closing Date and, if later, the Option Closing Date, the Prospectus did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The foregoing representations and warranties in this Section 3(b) do not apply to any statements or omissions made in reliance on and in conformity with information relating to any Underwriter furnished in writing to the Company by the Underwriters specifically for inclusion in the Registration Statement or Prospectus or any amendment or supplement thereto. The Company acknowledges that the statements set forth in the first two paragraphs under the heading "Underwriting" in the Prospectus

constitute the only information relating to any Underwriter furnished in writing to the Company by the Underwriters specifically for inclusion in the Registration Statement.

c. The Company is, and each of BTRL Contracts and Services, Inc. and BBI North American Clinical Laboratories, Inc. (collectively, the "SUBSIDIARIES") are, and at the Closing Date and, if later, the Option Closing Date will be, duly organized, validly existing and in good standing under the laws of the Commonwealth of Massachusetts. The Company and the Subsidiaries have, and at the Closing Date and, if later, the Option Closing Date will have, full power and authority to conduct all the activities conducted by them, to own or lease all the assets owned by or leased by them, and to conduct their business as described in the Registration Statement and the Prospectus. The Company is, and the Subsidiaries are, and at the Closing Date and, if later, the Option Closing Date they will be, duly licensed or qualified to do business and in good standing as foreign corporations in all jurisdictions in which the nature of the activities conducted by them or the character of the assets owned or leased by them makes such license or qualification necessary, except to the extent that the failure to be so qualified or be in good standing would not materially and adversely affect the Company and its Subsidiaries, taken as a whole, their business, properties, business prospects, condition (financial or otherwise) net worth or results of operations. The Subsidiaries are the only subsidiaries (as defined in the Act) of the Company. Except as set forth in the Prospectus, the Company and the Subsidiaries (i) do not own, and at the Closing Date and, if later, the Option Closing Date will not own, directly or indirectly, any shares of stock or any other equity or long-term debt securities of any corporation (except, in the case of the Company, for the Subsidiaries) or have any equity interest in any corporation, firm, partnership, joint venture, association or other entity and (ii) are not, and at the Closing Date and, if later, the Option Closing Date will not be, engaged in any discussions or a party to any agreement or understanding, written or oral, regarding the acquisition of an interest in any corporation, firm, partnership, joint venture, association or other entity where such discussions, agreements or understandings would require amendment to the Registration Statement pursuant to applicable securities laws. Complete and correct copies of the articles of incorporation, the bylaws or other organizational documents of the Company and the Subsidiaries and all amendments thereto have been delivered to the Representatives, and no changes therein will be made subsequent to the date hereof and prior to Closing Date or, if later, the Option Closing Date.

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d. The Company has authorized, issued and outstanding capital stock as set forth under the caption "Capitalization" in the Prospectus. All of the outstanding shares of capital stock of the Company have been duly authorized and validly issued, are fully paid and nonassessable, were issued in compliance with all applicable state and federal securities laws, were not issued in violation of or subject to any preemptive rights or other rights to subscribe for or purchase securities, and conform to the description thereof contained in the Prospectus; the Shares have been duly authorized and when issued and paid for as contemplated herein will be validly issued, fully paid and nonassessable and the Shares will conform to the description thereof contained in the Prospectus; the shares of Common Stock issuable by the Company upon the exercise of the Representatives' Warrants have been duly authorized, and, when issued and paid for in accordance with the terms of the Representatives' Warrants, will be validly issued, fully paid and nonassessable; and no preemptive rights or other rights to subscribe for or purchase exist with respect to the issuance and sale of the Shares or with respect to the Common Stock issuable upon the exercise of the Representatives' Warrants. The Company has reserved and will keep available for the exercise of the Representatives' Warrants such number of authorized but unissued shares of Common Stock to permit the exercise in full of the Representatives' Warrants. The description of the capital stock of the Company in the Registration Statement and the Prospectus is, and at the Closing Date and, if later, the Option Closing Date will be, complete and accurate in all respects. Except as set forth in the Prospectus, the Company does not have outstanding, and at the Closing Date and, if later, the Option Closing Date will not have outstanding, any options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or any contracts or commitments to issue or sell, any shares of Common Stock, or any such warrants, convertible securities or obligations. The description of the Company's stock option and other stock plans or arrangements, and the options or other rights granted or exercised thereunder, set forth in the Prospectus, accurately and fairly presents the information required to be shown with respect to such plans, arrangements, options and rights. No further approval or authority of the shareholders or the Board of Directors of the Company will be required for the issuance and sale of the Shares by the Company as contemplated herein. The Company owns of record and beneficially, free and clear of any lien. adverse claim, security interest, equity or other encumbrance, the capital stock of the Subsidiaries and there are no other owners of any securities of any kind issued by or related to the Subsidiaries.

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e. The financial statements and schedules included in the Registration Statement or the Prospectus comply in all material respects with the requirements of the Act and the Rules and Regulations, and present fairly the financial condition of the Company and the Subsidiaries as of the respective dates thereof and the results of operations, changes in shareholders' equity and cash flows of the Company for the respective periods covered thereby, all in conformity with generally accepted accounting principles applied on a consistent basis throughout the entire period involved. No other financial statements or schedules of the Company are required by the Act or the Rules and Regulations to be included in the Registration Statement or the Prospectus. Coopers & Lybrand L.L.P., who have reported on such financial statements and schedules, are independent accountants with respect to the Company as required by the Act and the Rules and Regulations. The summary financial and statistical data included in the Registration Statement present fairly the information shown therein and have been compiled on a basis consistent with the financial statements presented therein.

f. Subsequent to the respective dates as of which information is given in the Registration Statement and the Prospectus and prior to the Closing Date and, if later, the Option Closing Date, except as set forth in or contemplated by the Registration Statement and the Prospectus, (i) there has not been and will not have been any change in the capitalization of the Company (other than in connection with the exercise of outstanding options to purchase the Company's Common Stock granted pursuant to the Company's stock option plans from the reserves as described in the Registration Statement, which shares received upon exercise will be subject to the lock-up agreements described in Section 5(i) below), or any material adverse change, or any development which could reasonably be expected to involve a prospective material adverse change, in the business, properties, business prospects, condition (financial or otherwise), net worth or results of operations of the Company and the Subsidiaries, taken as a whole, arising for any reason whatsoever, (ii) the Company and the Subsidiaries, taken as a whole, have not incurred nor will they incur, except in the ordinary course of business as described in the Prospectus, any material liabilities or obligations, direct or contingent, nor have they entered into nor will they enter into, except in the ordinary course of business as described in the Prospectus, any material transactions other than pursuant to this Agreement and the transactions referred to herein, and (iii) the Company has not and will not have paid or declared any dividends or other distributions of any kind on any class of its capital stock.

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- g. Neither the Company nor any of the Subsidiaries is, and upon the sale of the Shares to be issued and sold by it hereunder and application of the net proceeds from such sale as described in the Prospectus under the caption "Use of Proceeds" will be, an "investment company" or an "affiliated person" of, or "promoter" or "principal underwriter" for, an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended.
- h. There are no actions, suits or proceedings pending or, to the knowledge of the Company, threatened against or affecting the Company or any Subsidiary, or any of their officers in their capacity as such, nor any basis therefor, before or by any federal or state court, commission, regulatory body, administrative agency or other governmental body, domestic or foreign, wherein an unfavorable ruling, decision or finding would materially and adversely affect the Company and the Subsidiaries, taken as a whole, or their respective, business, properties, business prospects, condition (financial or otherwise), net worth or results of operations. Neither the Company nor any of the Subsidiaries is involved in any strike, job action or labor dispute, and to the Company's best knowledge no such action or dispute is threatened.
- i. The Company and the Subsidiaries have, and at the Closing Date and, if later, the Option Closing Date will have, performed all their obligations required to be performed by them as of such date, and neither the Company nor any Subsidiary is, and at the Closing Date nor, if later, the Option Closing Date will be, nor with the passage of time or the giving of notice or both would be, in violation of its certificate of incorporation or by-laws or other organizational documents, or of any law, ordinance, administrative or governmental rule or regulation applicable to the Company or any Subsidiary, or of any judgment, order or decree of any court or governmental agency or body or of any arbitrator having jurisdiction over the Company or the Subsidiaries, or in default in the performance or observance of any obligation, agreement, covenant or condition contained in any mortgage, loan agreement, note, bond, debenture, credit agreement or any other evidence of indebtedness to which any of them a party or by which their property is bound or affected, which violation or default might materially and adversely affect the Company and the Subsidiaries, taken as a whole, or their business, properties, business prospects, condition (financial or otherwise), net worth or results of operations. To the Company's best knowledge, no other party under any contract or other instrument to which the Company or its Subsidiaries are a party is in default in any respect thereunder, which default would materially and

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adversely affect the Company and the Subsidiaries, taken as a whole, or their business, properties, business prospects, condition (financial or otherwise), net worth or results of operations. The Company and the Subsidiaries are not, and at the Closing Date and, if later, the Option Closing Date will not be, in violation of any provision of their respective articles of incorporation, bylaws or other organizational documents.

j. No consent, approval, authorization or order of, or any filing or declaration with, any court or governmental agency or body is required for the issuance and sale of the Shares and the Representatives' Warrants by the Company, the execution, delivery or performance of the Agreement and the Representatives' Warrants by the Company or the consummation by the Company of the transactions on its part contemplated herein and in the Representatives' Warrants, except such as have been obtained under the Act or the Rules and Regulations and such as may be required under state securities or Blue Sky laws or the bylaws and rules of the National Association of Securities Dealers, Inc. (the "NASD") in connection with the purchase and distribution by the Underwriters of the Shares.

k. The Company has full corporate power and authority to enter into this Agreement and the Representatives' Warrants, to issue and sell the Shares and the Representatives' Warrants and to perform its respective obligations thereunder. The execution, delivery and performance of this Agreement and the Representatives' Warrants has been duly and validly authorized by the Company, and each of this Agreement and the Representatives' Warrants has been duly executed and delivered by the Company and constitutes a valid and binding

agreement of the Company, enforceable against the Company in accordance with its terms. The performance of this Agreement and the Representatives' Warrants and the consummation of the transactions contemplated hereby and thereby will not, with or without notice, the passage of time or both, result in the imposition of any lien, charge or encumbrance upon any of the assets of the Company or any Subsidiary pursuant to the terms or provisions of, or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or give any party a right to terminate any of its obligations under, or result in the acceleration of any obligation under the articles of incorporation, bylaws or other organizational documents of the Company and any Subsidiary, any indenture, mortgage, deed of trust, voting trust agreement, loan agreement, bond, debenture, note agreement or other evidence of indebtedness, lease, contract or other agreement or instrument to

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which the Company or any Subsidiary is a party or by which the Company or any Subsidiary or any of their properties is bound or affected, or violate or conflict with any judgment, ruling, decree, order, statute, rule or regulation of any court or other governmental agency or body applicable to the business or properties of the Company and any Subsidiary, presently in effect, a breach or violation of which, a default under which, a termination of which, an acceleration under which, or a conflict with which would materially and adversely affect the Company and any Subsidiary, taken as a whole, and their business, properties, business prospects, condition (financial or otherwise), net worth or results of operations.

1. The Company and the Subsidiaries have good and marketable title to all properties and assets described in the Prospectus as owned by them, free and clear of all liens, charges, encumbrances or restrictions, except such liens, charges, encumbrances or restrictions as are described in the Prospectus and those which, individually and in the aggregate, are not material in amount or which, individually and in the aggregate, do not adversely affect the use made or proposed to be made of such properties and assets by the Company and the Subsidiaries. The Company and the Subsidiaries, as lessees, have valid, subsisting and enforceable leases for the properties described in the Prospectus as leased by them. The agreements to which the Company or any Subsidiary are a party described in the Prospectus are valid agreements, enforceable by the Company or any Subsidiary (as applicable), except as the enforcement thereof may be limited by bankruptcy and laws relating to the rights and remedies of creditors generally or by the availability of general equitable remedies. The Company any the Subsidiaries own or lease all such properties as are necessary to their operations as now conducted or as proposed to be conducted.

m. There is no document or contract of a character required to be described in the Registration Statement or the Prospectus or to be filed as an exhibit to the Registration Statement which is not described or filed as required. All such contracts to which the Company or any Subsidiary is a party have been duly authorized, executed and delivered by the Company or the Subsidiary, constitute valid and binding agreements of the Company or the Subsidiary and are enforceable against the Company or the Subsidiary and by the Company or the Subsidiary against the other parties thereto in accordance with the terms thereof, except as to (i) bankruptcy and laws relating to the rights and remedies of creditors generally and (ii) the availability of equitable remedies.

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n. No statement, representation, warranty or covenant made by the Company in this Agreement or made in any certificate or document required by Section 5 of this Agreement to be delivered to the Underwriters was or will be, when made, inaccurate, untrue or incorrect.

- o. Neither the Company nor any of its directors, officers or controlling persons has taken, directly or indirectly, any action designed, or which might reasonably be expected, to cause or result, under the Act or otherwise, in, or which has constituted, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Shares.
- p. No holder of securities of the Company has rights to the registration of any securities of the Company because of the filing of the Registration Statement or consummation of the transactions contemplated by this Agreement which rights have not been validly waived by the holder or otherwise satisfied as of the date hereof. Except as disclosed in the Prospectus under the caption "Shares Eligible For Future Sale," no person has the right to require registration under the Act of any Common Stock or other securities of the Company.
- q. The Common Stock is listed and duly admitted to trading on the Nasdaq National Market (the "NASDAQ NATIONAL MARKET"), and the Company has received notification that the quotation by the Nasdaq National Market of the Shares has been approved, subject to official notice of issuance of the Shares.
- r. (i) The Company and the Subsidiaries, taken as a whole, have all trademarks, trade names, patent rights, copyrights, licenses, approvals and governmental authorizations necessary to conduct their business as now conducted, except where the failure to have any such right would not have a material and adverse effect on the Company and the Subsidiaries, taken as a whole, or their respective business, properties, business prospects, condition (financial or otherwise), net worth or results of operations; (ii) the Company and the Subsidiaries are not infringing any copyrights, trade secrets or other similar rights, trademarks, trade name rights or patent rights of others where such infringement would have a material and adverse effect on the Company and the Subsidiaries, taken as a whole, or their respective business, properties, business prospects, condition (financial or otherwise), net worth or results of operations; and (iii) no claim has been made against the Company regarding trademark, trade name, patent, copyright, license, trade secret or other infringement which would have a

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material and adverse effect on the Company and the Subsidiaries, taken as a whole, or their respective business, properties, business prospects, condition (financial or otherwise), net worth or results of operations.

- s. The Company has filed all federal, state, local and foreign income tax returns which have been required to be filed, which returns are complete and correct in all material respects, and has paid all taxes and assessments received by it to the extent that such taxes or assessments have become due. All payroll withholdings required to be made by the Company or any Subsidiary with respect to employees have been made. The charges, accruals and reserves on the books of the Company and the Subsidiaries in respect of any tax liability for any years not finally determined are adequate to meet any assessments or reassessments for additional taxes. The Company has no tax deficiency which has been or might be asserted or threatened against the Company which could have a material and adverse effect on the Company or its business, properties, business prospects, condition (financial or otherwise), net worth or results of operations.
- t. The Company and its Subsidiaries own or possess all authorizations, approvals, orders, licenses, registrations, certificates and permits of and from, and have made all declarations and filings with, all governmental regulatory officials and bodies necessary to conduct their business as contemplated in the Prospectus, except where the failure to own or possess all such authorizations, approvals, orders, licenses, registrations, certificates and permits or make such declarations and filings would not, individually or in the aggregate, materially and adversely affect the Company and the Subsidiaries, taken as a whole, or their respective business, properties, business prospects, condition (financial or otherwise), net worth or results of operations. There is no proceeding pending or, to the knowledge of the Company, threatened, or any basis therefor known to the Company, which may cause or allow any such

authorization, approval, order, license, registration, certificate or permit to be revoked, withdrawn, canceled, suspended or not renewed or result in any material impairment of the rights thereunder; and the Company and its Subsidiaries are conducting their business in compliance with all laws, rules and regulations applicable thereto, except where any such failure to comply would not have a material adverse effect on the Company and the Subsidiaries, taken as a whole, or their respective business, properties, business prospects, condition (financial or otherwise), net worth or results of operations. Except as described in the Registration Statement and the Prospectus, none of such authorizations, approvals, orders, licenses, registrations, certificates or permits

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contains any restriction that is materially burdensome to the Company and the Subsidiaries, taken as a whole.

u. The Company and the Subsidiaries maintain insurance of the types and in the amounts generally deemed adequate for their respective business, including, but not limited to, insurance covering real and personal property owned or leased by the Company and the Subsidiaries against theft, damage, destruction, acts of vandalism and all other risks customarily insured against, all of which insurance is in full force and effect. The Company and the Subsidiaries are in compliance with the terms of such policies in all material respects. The Company and the Subsidiaries have not been refused any insurance coverage sought or applied for; and the Company has no reason to believe that it and the Subsidiaries will not be able to renew their existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue their business at a cost that would not have a material adverse effect on the Company and the Subsidiaries, taken as a whole, or their business, properties, business prospects, condition (financial or otherwise), net worth or results of operations. There are no material claims by the Company or any of the Subsidiaries under any such policy as to which any insurance company is denying liability or defending under a reservation of rights clause.

v. The Company and the Subsidiaries are (i) in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("ENVIRONMENTAL LAWS"), (ii) have received all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective business and (iii) are in compliance with all terms and conditions of any such permit, license or approval, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals would not, singly or in the aggregate, have a material adverse effect on the Company and the Subsidiaries, taken as a whole, or their respective business, properties, business prospects, condition (financial or otherwise), net worth or results of operations.

w. In the ordinary course of its business, the Company conducts a periodic review of the effect of Environmental Laws on the business, operations and properties of the Company and the Subsidiaries in the course of which it

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identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties). On the basis of such review, the Company has reasonably concluded that such associated costs and liabilities would not, singly or in the aggregate, have a material adverse effect on the Company and

the Subsidiaries, taken as a whole, or their respective business, properties, business prospects, condition (financial or otherwise), net worth or results of operations.

- x. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any employee or agent of the Company or any Subsidiary, has at any time during the last five years (i) made any unlawful contribution to any candidate for foreign office, or failed to disclose fully any contribution in violation of law, or (ii) made any payment to any federal or state governmental officer or official, or other person charged with similar public or quasi-public duties, other than payments required or permitted by the laws of the United States or any jurisdiction thereof.
- y. The Company has not distributed and, prior to the later to occur of (i) the Closing Date or (ii) completion of the distribution of the Shares, will not distribute without the prior written consent of the Underwriters any offering material in connection with the offering and sale of the Shares other than the Registration Statement, any Preliminary Prospectus, the Prospectus or other materials, if any, permitted by the Act and the Rules and Regulations. The Company is not involved in any labor dispute and, to the knowledge of the Company, no such dispute is threatened.
- z. Neither the Company nor its officers, directors, employees or agents have taken or will take, directly or indirectly, (i) any action designed to cause or to result in, or that has constituted or which might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Shares, or (ii) since the filing of the Registration Statement, except in connection with the sale of the Shares, (A) sold, bid for, purchased, attempted to induce any person to purchase, or paid anyone any compensation for soliciting the purchase of, the Shares or (B) paid or agreed to pay any person any compensation for soliciting another to purchase any other securities of the Company.

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aa. The Company has obtained from each of its directors, officers and the other shareholders specified by the Representatives a written agreement that, for a period of 180 days from the date of the Prospectus, he, she or it will not, without the prior written consent of Oscar Gruss, offer, sell, contract to sell, grant any option for the sale of, or otherwise dispose of, directly or indirectly, any shares of Common Stock or any security convertible into, or exchangeable or exercisable for, shares of Common Stock or other securities of the Company.

bb. The Company has complied with all provisions of Florida Statutes, ss. 517.075, relating to issuers doing business with Cuba.

cc. The Company has no liability or obligation of any nature (absolute, accrued, contingent or otherwise) which is not fully reflected or adequately reserved against in the balance sheet at June 30, 1996, except for liabilities (i) incurred in the ordinary course of business and not required under generally accepted accounting procedures to be reflected on the balance sheet, (ii) incurred since June 30, 1996 in the ordinary course of business and consistent with past practice, or (iii) described in the Prospectus. The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (A) transactions are executed in accordance with management's general or specific authorizations; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain accounting for assets; (C) access to assets is permitted only in accordance with management's general or specific authorization; (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences and (E) reserves for obsolete inventory, bad debts and sales returns and allowances are adequate.

Any certificate signed by an officer of the Company and delivered to the Underwriters or counsel for the Underwriters at a closing hereunder shall be deemed a representation and warranty of the Company to each Underwriter as to

#### 4. AGREEMENTS OF THE COMPANY

The Company agrees with the several Underwriters as follows:

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- a. The Company will not, either prior to the Effective Date or thereafter during such period as the Prospectus is required by law to be delivered in connection with sales of the Shares by an Underwriter or dealer, file any amendment or supplement to the Registration Statement or the Prospectus, unless a copy thereof shall first have been submitted to the Underwriters within a reasonable period of time prior to the filing thereof and the Underwriters shall not have objected thereto in good faith.
- b. The Company will use its best efforts to cause the Registration Statement to become effective, and will notify the Underwriters and will confirm such advice in writing. (i) when the Registration Statement has become effective and when any post-effective amendment thereto becomes effective, (ii) of any request by the Commission for amendments or supplements to the Registration Statement or the Prospectus or for additional information, (iii) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose or the threat thereof, (iv) of the happening of any event during the period mentioned in the third sentence of Section 4(e) that makes any statement made in the Registration Statement or the Prospectus untrue or that requires the making of any changes in the Registration Statement or the Prospectus in order to make the statements therein not misleading, and (v) of receipt by the Company or any representative or attorney of the Company of any other communication from the Commission relating to the Company, the Registration Statement, any preliminary prospectus, the Term Sheet or the Prospectus. If at any time the Commission shall issue any order suspending the effectiveness of the Registration Statement, the Company will make every reasonable effort to obtain the withdrawal of such order at the earliest possible moment. If the Company has omitted any information from the Registration Statement pursuant to Rule 430A of the Rules and Regulations, the Company will use its best efforts to comply with the provisions of, and make all requisite filings with the Commission pursuant to, said Rule 430A and, if a Term Sheet is used, Rule 434 and to notify the Underwriters promptly of all such filings.
- c. The Company will furnish to the Underwriters without charge three signed copies of the Registration Statement and of any post-effective amendment thereto, including financial statements and schedules, and all exhibits thereto, and will furnish to the Underwriters, without charge, for transmittal to each of the other Underwriters, such number of conformed copies of the Registration Statement and

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any post-effective amendment thereto, including financial statements and schedules, but without exhibits, as you may reasonably request.

- d. The Company will comply with all the provisions of any undertakings contained in the Registration Statement.
- e. On the Effective Date, and thereafter from time to time, the Company will deliver to each of the Underwriters, without charge, as many copies of the Prospectus or any amendment or supplement thereto as the Representatives may reasonably request. The Company consents, subject to the provisions of the following sentence, to the use of the Prospectus or any amendment or supplement thereto by the several Underwriters and by all dealers to whom the Shares may be sold, both in connection with the offering or sale of the Shares and for any period of time thereafter during which the Prospectus is required by law to be

delivered in connection therewith. If during the nine-month period referred to in Section 10(a)(3) of the Act any event shall occur which in the judgment of the Company or counsel to the Underwriters should be set forth in the Prospectus in order to make any statement therein, in light of the circumstances under which it was made, not misleading, or if it is necessary to supplement or amend the Prospectus to comply with law, the Company will forthwith prepare and duly file with the Commission an appropriate supplement or amendment thereto, and will deliver to each of the Underwriters, without charge, such number of copies of such supplement or amendment to the Prospectus as the Representatives may reasonably request and, in case any Underwriter is required to deliver a prospectus after such nine month period, the Company upon request, but at the expense of such Underwriter, will promptly prepare such amendment or amendments to the Registration Statement and Prospectus as may be necessary to permit compliance with the requirements of Section 10(a)(3) of the Act.

f. Prior to any public offering of the Shares, the Company will cooperate with the Underwriters and counsel to the Underwriters in connection with the registration or qualification of the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions as the Underwriters may request; provided that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action which would subject it to general service of process in any jurisdiction where it is not now so subject.

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- g. During the period of five years commencing on the Effective Date, the Company will furnish to the Representatives, and each other Underwriter who may so request, copies of such financial statements and other periodic and special reports as the Company may from time to time distribute generally to the holders of any class of its capital stock, and will furnish to the Representatives, and each other Underwriter who may so request, a copy of each annual or other report it shall be required to file with the Commission.
- h. The Company will make generally available to holders of its securities as soon as may be practicable but in no event later than the last day of the fifteenth full calendar month following the calendar quarter in which the Effective Date falls, an earnings statement (which need not be audited but shall be in reasonable detail) for the applicable 12-month period after the Effective Date, satisfying the provisions of Section 11(a) of the Act (including Rule 158 of the Rules and Regulations).
- i. Whether or not the transactions contemplated by this Agreement are consummated or this Agreement is terminated, the Company will pay, or reimburse if paid by the Underwriters all costs and expenses incident to the performance of the obligations of the Company under this Agreement, including but not limited to costs and expenses of or relating to (i) the preparation, printing and filing of the Registration Statement and exhibits to it, each preliminary prospectus, Term Sheet, Prospectus and any amendment or supplement to the Registration Statement or Prospectus, (ii) the preparation and delivery of certificates representing the Shares, (iii) the printing of this Agreement, the Agreement among Underwriters, any Dealer Agreements and any Underwriters' Questionnaires, (iv) furnishing (including costs of shipping and mailing) such copies of the Registration Statement, the Prospectus, the Term Sheet and any preliminary prospectus, and all amendments and supplements thereto, as may be requested for use in connection with the offering and sale of the Shares by the Underwriters or by dealers to whom Shares may be sold, (v) the listing of the Shares on the Nasdaq National Market, (vi) any filings required to be made by the Underwriters with the NASD, including the fees, disbursements and other charges of counsel for the Underwriters in connection therewith, (vii) the registration or qualification of the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions designated pursuant to Section 4(f), including the fees, disbursements and other charges of counsel to the Underwriters in connection therewith, and the preparation and printing of preliminary, supplemental and final Blue Sky memoranda, (viii) fees, disbursements

and other charges to the Company (but not those of counsel for the Underwriters, except as otherwise provided herein), (ix) the transfer agent for the Shares, (x) informational meetings and (xi) the "tombstone" advertisement with respect to the Shares. In addition to the Company's responsibility for payment of the foregoing expenses, the Company shall pay to the Underwriters a non-accountable expense allowance equal to one percent (1%) of the gross proceeds from the sale of the Shares (including in such amount the proceeds from any sale of the Option Shares), of which \$40,000 has been paid to date. If the offering is not consummated, the Underwriters will be entitled to reimbursement for actual out-of-pocket expenses, and will return to the Company any unused portion of the \$40,000. If the Offering is not consummated, the Underwriters will return to the Company any unused portion of the pre-paid expense allowance.

- j. If this Agreement shall be terminated by the Company pursuant to any of the provisions hereof (otherwise than pursuant to Section 8 hereof) or if for any reason the Company shall be unable to perform its obligations hereunder, the Company will reimburse the several Underwriters for all reasonable out-of-pocket expenses (including the fees, disbursements and other charges of counsel to the Underwriters) reasonably incurred by them in connection herewith. The Company shall reimburse Oscar Gruss within five days of termination of this Agreement.
- k. The Company will not at any time, directly or indirectly, take any action designed, or which might reasonably be expected, to cause or result in, or which will constitute, stabilization of the price of the shares of Common Stock to facilitate the sale or resale of any of the Shares.
- 1. The Company will apply the net proceeds from the offering and sale of the Shares in the manner set forth in the Prospectus under "Use of Proceeds," and shall file such reports with the Commission with respect to the sale of the Company Shares and the application of the proceeds therefrom as may be required in accordance with Rule 463 under the Act.
- m. During the period of 180 days commencing at the Closing Date, without the prior written consent of Oscar Gruss, which consent may be withheld in the sole discretion of Oscar Gruss and other than pursuant to the exercise of outstanding warrants and stock options or otherwise pursuant to the Company's stock option plan disclosed in the Prospectus, the Company will not issue, offer, sell, grant options to purchase or otherwise dispose of any of the Company's equity

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securities or any other securities convertible into or exchangeable with its Common Stock or other equity security. During a period of 180 days after the Closing Date, the Company will not file a registration statement for the purpose of registering any securities of the Company without the prior written consent of Oscar Gruss, which consent may be withheld in its sole discretion. The Company will not, for a period of two years from the date hereof, without the prior written approval of Oscar Gruss, propose or enter into any arrangement not existing on the date hereof, for the granting or awarding of the stock options.

n. The Company will cause each of its officers, directors, and shareholders holding in the aggregate at least \_\_\_\_\_ shares of Common Stock to enter into lock-up agreements with the Underwriters to the effect that they will not, without the prior written consent of Oscar Gruss, sell, contract to sell or otherwise dispose of any shares of Common Stock or rights to acquire such shares according to the terms set forth in Exhibit B hereto.

# 5. CONDITIONS OF THE OBLIGATIONS OF THE UNDERWRITERS

The obligations of each Underwriter hereunder are subject to the

- a. Notification that the Registration Statement has become effective shall be received by the Underwriters not later than 5:00 p.m., New York City time, on the date of this Agreement or at such later date and time as shall be consented to in writing by the Underwriters and all filings required by Rule 424, Rule 430A and Rule 434 of the Rules and Regulations shall have been made.
- b. (i) No stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for the purpose shall be pending or threatened by the Commission, (ii) no order suspending the effectiveness of the Registration Statement or the qualification or registration of the Shares under the securities or Blue Sky laws of any jurisdiction shall be in effect and no proceeding for such purpose shall be pending before or threatened or contemplated by the Commission or the authorities of any such jurisdiction, (iii) any request for additional information on the part of the staff of the Commission or any such authorities shall have been complied with to the satisfaction of the staff of the Commission or such authorities, and (iv) after the date hereof no amendment or supplement to the Registration Statement or the Prospectus shall have been filed

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unless a copy thereof was first submitted to the Underwriters and the Underwriters do not object thereto in good faith, and the Underwriters shall have received certificates, dated the Closing Date and the Option Closing Date and signed by the Chief Executive Officer and the Chief Financial Officer of the Company (who may, as to proceedings threatened, rely upon the best of their knowledge), to the effect of clauses (i), (ii) and (iii) of this Section 5(b).

- c. Since the respective dates as of which information is given in the Registration Statement and the Prospectus, (i) there shall not have been a material adverse change, or any development involving a prospective material adverse change, in the general affairs, business, business prospects, properties, management, condition (financial or otherwise), net worth or results of operations of the Company or any Subsidiary, whether or not arising from transactions in the ordinary course of business, in each case other than as described in or contemplated by the Registration Statement and the Prospectus, and (ii) neither the Company nor any Subsidiary shall have sustained any material loss or interference with its business or properties from fire, explosion, flood, earthquake or other casualty, whether or not covered by insurance, or from any labor dispute or any court of legislative or other governmental action, order or decree, which is not described in the Registration Statement and the Prospectus, if in the judgment of the Underwriters any such development makes it impracticable or inadvisable to consummate the sale and delivery of the Shares by the Underwriters at the public offering price.
- d. Since the respective dates as of which information is given in the Registration Statement and the Prospectus, there shall have been no litigation or other proceeding instituted or threatened against the Company or any Subsidiary or any of their respective officers or directors in their capacities as such, before or by any federal, state or local court, commission, regulatory body, administrative agency or other governmental body, domestic or foreign, in which litigation or proceeding an unfavorable ruling, decision or finding would materially and adversely affect the business, properties, business prospects, condition (financial or otherwise), net worth or results of operations of the Company and the Subsidiaries, taken as a whole.
- e. Each of the representations and warranties of the Company contained herein shall be true and correct in all material respects at the Closing Date and, with respect to the Option Shares, at the Option Closing Date, and all

covenants and agreements contained herein to be performed on the part of the Company and all conditions contained herein to be fulfilled or complied with by the Company at or prior to the Closing Date and, with respect to the Option Shares, at or prior to the Option Closing Date, shall have been duly performed, fulfilled or complied with.

- f. The Underwriters shall have received an opinion, dated the Closing Date and, with respect to the Option Shares, the Option Closing Date, satisfactory in form and substance to the Underwriters and counsel for the Underwriters, from Brown, Rudnick, Freed & Gesmer, P.C., counsel to the Company, covering the following matters:
- (i) the Company has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Massachusetts, has the corporate power and authority to own its property and to conduct its business as described in the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification except where the failure so to qualify does not have a material adverse effect on the business, properties, business prospects, condition (financial or otherwise), net worth or results of operations of the Company;
- (ii) each of the Subsidiaries has been duly organized and is validly existing as a corporation in good standing under its jurisdiction of organization and is qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification except where the failure so to qualify does not have a material adverse effect on the business, properties, business prospects, condition (financial or otherwise), net worth or results of operations of such Subsidiary. Except for the Subsidiaries, the Company does not have any active subsidiaries or own or control any other corporation, association, or other business entity;
- (iii) the authorized capital stock of the Company conforms to the description thereof contained in the Prospectus;
- (iv) the authorized, issued and outstanding capital stock of the Company is as set forth under the caption "Capitalization" in the Prospectus as of the date therein; the shares of Common Stock outstanding prior to the issuance

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of the Firm Shares (or, with respect to the opinion to be delivered on the Option Closing Date, prior to the issuance of the Company Option Shares) have been duly authorized and are validly issued, fully paid and nonassessable, have been issued pursuant to exemptions from the registration and qualification requirements of federal and applicable state securities laws, were not issued in violation of or subject to any preemptive rights or, to the best of such counsel's knowledge, other rights to subscribe for or purchase any securities, and conform to the description thereof contained in the Prospectus;

- (v) the specimen certificate evidencing the Company's Common Stock filed as an exhibit to the Registration Statement is in due and proper form under Massachusetts law; the Shares have been duly authorized and, when the certificates evidencing the Shares have been issued and delivered in accordance with the terms of this Agreement, the Shares will be validly issued, fully paid and nonassessable; the issuance of such Shares is not subject to any preemptive rights or, to the best of such counsel's knowledge, other rights to subscribe for or purchase securities; and the Common Stock conforms in all material respects to the description thereof contained in the Prospectus;
- (vi) the Representatives' Warrants have been duly authorized, executed and delivered by the Company and the Company has all requisite corporate power and authority to execute the Representatives' Warrants; the Representatives' Warrants are enforceable against the Company in accordance with their terms; the shares of Common Stock issuable upon the exercise of the

Representatives' Warrants have been reserved for such issuance and, when issued in accordance with the terms of the Representatives' Warrants, will be duly authorized, validly issued, fully paid and nonassessable and free of preemptive rights and, to the best of such counsel's knowledge, other rights to subscribe for or purchase securities; and the Representatives' Warrants conform in all material respects to the description thereof contained in the Prospectus;

(vii) the Registration Statement has become effective under the Act, and, to the best of such counsel's knowledge, no stop order suspending the effectiveness of the Registration Statement or preventing the use of the Prospectus has been issued and no proceedings for that purpose have been instituted or are pending or, to the best of such counsel's knowledge, threatened by the Commission; any required filing of the Prospectus or of the Term Sheet and any supplement thereto pursuant to Rule 424(b) or Rule 434 of the Rules and

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Regulations has been made in the manner and within the time period required by such Rule 424(b) and Rule 434;

- (viii) the Registration Statement and the Prospectus and any supplements or amendments thereto (except for financial statements, schedules and financial information included therein, as to which such counsel need not express any opinion) comply as to form in all material respects with the Act and the Rules and Regulations.
- (ix) this Agreement has been duly authorized, executed and delivered by the Company, and the Company has all requisite corporate power and authority to enter into this Agreement and consummate the transactions contemplated hereby;
- (x) this Agreement is a valid and binding agreement of the Company, enforceable against the Company in accordance with its terms, except as to (A) rights to indemnity and contribution thereunder which may be limited by applicable law, (B) bankruptcy and laws relating to the rights and remedies of creditors generally, and (C) the availability of equitable remedies; the execution and delivery by the Company of, and the performance by the Company of its obligations under, this Agreement and the Representatives' Warrants do not contravene any provision of applicable law, statute, rule or regulation or the articles of incorporation, bylaws or other organizational documents of the Company and the Subsidiaries or any agreement or other instrument binding upon the Company or any Subsidiary that is filed as an exhibit to the Registration Statement or is known to such counsel, or any judgment or decree known to such counsel of any governmental body, agency or court having jurisdiction over the Company or any Subsidiary, presently in effect and a breach or violation of which, a default under which, a termination of which, an acceleration under which, or a conflict with which would materially and adversely affect the Company and the Subsidiaries, taken as a whole, or their business, properties, business prospects, financial condition or results of operations, and no consent, approval or authorization or order of, or qualification with, any governmental body or agency is required for the performance by the Company of its obligations under this Agreement and the Representatives' Warrants, except such as may have been obtained under the Act and the Exchange Act and such as required by the securities or Blue Sky laws of the various states in connection with the offer and sale of the Shares by the Underwriters;

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(xi) the statements in the Prospectus insofar as such statements constitute a summary of documents referred to therein or matters of law, fairly summarize in all material respects the information called for with

respect to such documents and matters of law;

- (xii) each of the Company and each Subsidiary has all necessary approvals, orders, licenses, registrations, certificates and permits of and from and have made all declarations and filings with all governmental regulatory officials and bodies necessary to conduct their business as described in the Prospectus, except where the failure to have all such authorizations, approvals, orders, licenses, registrations, certificates and permits or make such declarations or filings would not, individually or in the aggregate, have a material adverse effect on the business, properties, business prospects, condition (financial or otherwise), net worth or results of operations of the Company and the Subsidiaries taken as a whole.
- (xiii) neither the Company nor any of the Subsidiaries is an "investment company" or a person "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended.
- (xiv) to such counsel's knowledge, there are no legal or governmental proceedings pending or threatened to which the Company or any Subsidiary are a party or to which any of the properties of the Company is subject that are required to be described in the Registration Statement or the Prospectus and are not so described;
- (xv) to such counsel's knowledge, no holder of securities of the Company has rights which have not been waived to require the Company to register with the Commission shares of Common Stock or other securities as part of the offering contemplated hereby;
- (xvi) such counsel does not know of any contracts or documents required to be filed as exhibits to the Registration Statement or described in the Registration Statement or Prospectus or any supplements or amendments thereto which are required to be filed and are not so filed as required, and each description of such contracts and documents as is contained in the Registration Statement and Prospectus fairly presents in all material respects the information required under the Act and the Rules and Regulations;

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(xvii) as of the Effective Date, the Shares were duly authorized for quotation on the Nasdaq National Market upon official notice of issuance.

Such counsel shall also state that such counsel has participated in conferences with representatives of the Underwriters, officers and representatives of the Company and representatives of the independent certified public accountants of the Company, at which conferences the contents of the Registration Statement and the Prospectus and related matters were discussed and that, although such counsel is not passing upon and does not assume any responsibility for the accuracy, completeness or fairness of the statements contained in the Registration Statement and the Prospectus (except as set forth in Section 5(f)(xi)), on the basis of the foregoing, nothing has come to the attention of such counsel that leads them to believe that (except for financial statements, schedules and financial information, as to which such counsel need not express any belief), the Registration Statement and the Prospectus, as amended, included therein at the time the Registration Statement became effective contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading and the Prospectus, as amended or supplemented, if applicable, as of the date it was filed pursuant to the Rules and Regulations and as of the Closing Date or the Option Closing Date, as the case may be, contained any untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

In rendering the foregoing opinions, counsel may rely, to the extent they deem such reliance proper, on the opinions (in form and substance reasonably satisfactory to Underwriters' counsel) of other counsel reasonably acceptable to Underwriters' counsel as to matters governed by the laws of

jurisdictions other than the United States and the Commonwealth of Massachusetts, and as to matters of fact, upon certificates of officers of the Company and of government officials; provided that such counsel shall state that the opinion of any other counsel is in form satisfactory to such counsel and, in such counsel's opinion, such counsel and the Underwriters are justified in relying on such opinions of other counsel. Copies of all such opinions and certificates shall be furnished to counsel to the Underwriters on the Closing Date or the Option Closing Date, as the case may be.

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- g. The Underwriter shall have received an opinion, dated the Closing Date and, with respect to the Option Shares, the Option Closing Date, satisfactory in form and substance to the Underwriters and counsel for the Underwriters, from Buc and Beardsley, regulatory counsel for the Company, covering the following matters:
- (i) Any statements set forth in the Registration Statement and the Prospectus under the captions "Risk Factors -- Stringent Government Regulation" and "Business -- Government Regulation" (collectively, the "FDA PORTION") constitute an accurate summary in all material respects of restrictions applicable to the business of the Company arising under the Federal Food, Drug, and Cosmetic Act (the "FFDCA") or the regulations thereunder or the FDA regulation of the business or operations of the Company, or of any legal matters, documents or proceedings referred to therein and relating to the FFDCA or the FDA's regulation of the business or operations of the Company or the Company's compliance therewith.
- (ii) To counsel's knowledge, the Company has filed with the FDA for and received approval of all applications, licenses, registrations, and permits ("REGULATORY AUTHORIZATIONS") necessary to conduct the business of the Company described in the Registration Statement and the Prospectus.
- (iii) Based upon a review of the FDA Portion, counsel has no reason to believe that the information contained in the FDA Portion of the Registration Statement and the Prospectus at the time it became effective contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading or that on the Closing Date or the Option Closing Date, as the case may be, the information contained in the FDA Portion of the Prospectus or any amendments or supplements to the FDA Portion of the Prospectus contains any untrue statement of a material fact or omits to state any material fact necessary in order to make the statements therein not misleading.
- h. The Underwriters shall have received from the Company the duly executed Representatives' Warrants.
- i. The Underwriters shall have received an opinion, dated the Closing Date and, with respect to the Option Shares, the Option Closing Date, from Fulbright & Jaworski L.L.P., counsel to the Underwriters, with respect to the

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Registration Statement, the Prospectus and this Agreement, which opinion shall be satisfactory in all respects to the Underwriters.

j. The Underwriters shall have received, on or prior to the date hereof, agreements from all directors, officers and certain shareholders of the Company in the form attached as Exhibit B hereto holding in the aggregate at least \_\_\_\_ shares of Common Stock, stating that each of such persons, without the prior written consent of Oscar Gruss, will not offer to sell, contract to sell, sell, distribute, grant any option to purchase, pledge, hypothecate or

otherwise dispose of, directly or indirectly, any Common Stock, or any securities convertible into or exchangeable for Common Stock of the Company (including, without limitation, Common Stock of the Company that may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Commission and Common Stock that may be issued upon exercise of a stock option or warrant), or rights to acquire such Common Stock, for a period of 180 days from the date hereof.

- k. At the Effective Date and concurrently with the execution and delivery of this Agreement, Coopers & Lybrand L.L.P. shall have furnished to the Underwriters a letter, dated the date of its delivery, addressed to the Underwriters and in form and substance satisfactory to the Underwriters confirming that they are independent accountants with respect to the Company as required by the Act and the Rules and Regulations and with respect to certain financial and other statistical and numerical information contained in the Registration Statement. At the Closing Date, and, as to the Option Shares, the Option Closing Date, Coopers & Lybrand L.L.P. shall have furnished to the Underwriters a letter, dated the date of its delivery, which shall confirm, on the basis of a review in accordance with the procedures set forth in the letter from each accountant, that nothing has come to their attention during the period from the date of each letter referred to in the prior sentence to a date (specified in each letter) not more than five days prior to the Closing Date and the Option Closing Date, as the case may be, which would require any change in their letter dated the date hereof if it were required to be dated and delivered at the Closing Date and the Option Closing Date.
- 1. Concurrently with the execution and delivery of this Agreement and at the Closing Date and, with respect to the Option Shares, the Option Closing Date, there shall be furnished to the Underwriters a certificate, dated the date of its delivery, signed by the Chief Executive Officer and the Chief Financial Officer of

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the Company, in form and substance satisfactory to the Underwriters, to the effect that:

- (i) Each signer of such certificate has carefully examined the Registration Statement and the Prospectus and (A) as of the date of such certificate, the Registration Statement and the Prospectus do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading and (B) in the case of the certificate delivered at the Closing Date and the Option Closing Date, since the Effective Date no event has occurred as a result of which it is necessary to amend or supplement the Prospectus in order to make the statements therein not untrue or misleading in any material respect.
- (ii) Each of the representations and warranties of the Company contained in this Agreement were, when originally made, and are, at the time such certificate is delivered, true and correct.
- (iii) Each of the covenants required to be performed by the Company herein on or prior to the date of such certificate has been duly, timely and fully performed and each condition herein required to be satisfied or fulfilled on or prior to the date of such certificate has been duly, timely and fully satisfied or fulfilled.
- m. The Shares shall be qualified for sale in such jurisdictions as the Underwriters may, pursuant to the provisions of Section 4(f), reasonably request, and each such qualification shall be in effect and not subject to any stop order or other proceeding on the Closing Date or the Option Closing Date.
- n. Prior to the Closing Date, the Shares shall have been duly authorized for listing on the Nasdaq National Market upon official notice of issuance.
- o. The Company shall have furnished to the Underwriters such certificates, in addition to those specifically mentioned herein, as the

Underwriters may have reasonably requested as to the accuracy and completeness at the Closing Date and the Option Closing Date of any statement in the Registration Statement or the Prospectus, as to the accuracy at the Closing Date and the Option Closing Date of the representations and warranties of the Company herein, as to the performance by the Company of its obligations hereunder, or as to the fulfillment

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of the conditions concurrent and precedent to the obligations hereunder of the Underwriters.

#### 6. INDEMNIFICATION

a. The Company will indemnify and hold harmless each Underwriter, the directors, officers, employees and agents of each Underwriter and each person, if any, who controls, within the meaning of Section 15 of the Act or Section 20 of the Exchange Act, each Underwriter, from and against any and all losses, claims, liabilities, expenses and damages (including any and all investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted) to which they, or any of them, may become subject under the Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages (i) arise out of or are based on any untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, the Registration Statement or the Prospectus or any amendment or supplement to the Registration Statement or the Prospectus, or the omission or alleged omission to state in such document a material fact required to be stated in it or necessary to make the statements in it not misleading, (ii) arise out of or are based in whole or in part on any inaccuracy in the representations and warranties of the Company contained herein, or (iii) arise out of or are based upon any failure of the Company to perform its obligations hereunder or under law in connection with the transactions contemplated hereby; provided that the Company will not be liable to the extent that such loss, claim, liability, expense or damage arises from the sale of the Shares in the public offering to any person by an Underwriter and is based on an untrue statement or omission or alleged untrue statement or omission made in reliance on and in conformity with information relating to any Underwriter furnished in writing to the Company expressly for inclusion in the Registration Statement, the preliminary prospectus or the Prospectus, or any amendment or supplement thereto. The Company acknowledges that the statements set forth in the first two paragraphs under the heading "Underwriting" in the preliminary prospectus and the Prospectus constitute the only information relating to any Underwriter furnished in writing to the Company expressly for inclusion in the Registration Statement, the preliminary prospectus or the Prospectus. This indemnity will be in addition to any liability that the Company might otherwise have.

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b. Each Underwriter will indemnify and hold harmless the Company, each director of the Company and each officer of the Company who signs the Registration Statement and each person, if any, who controls, within the meaning of Section 15 of the Act or Section 20 of the Exchange Act, the Company, to the same extent as the foregoing indemnity from the Company to each Underwriter, as set forth in Section 6(a), but only insofar as losses, claims, liabilities, expenses or damages arise out of or are based on any untrue statement or omission or alleged untrue statement or omission made in reliance on and in conformity with information relating to any Underwriter furnished in writing to the Company expressly for use in the Registration Statement, the preliminary prospectus or the Prospectus, or any amendment or supplement thereto. The Company acknowledges that the statements set forth in the first two paragraphs under the heading "Underwriting" in the preliminary prospectus and the Prospectus constitute the only information relating to any Underwriter furnished in writing to the Company by the Underwriters expressly for inclusion in the

Registration Statement, the preliminary prospectus or the Prospectus. This indemnity will be in addition to any liability that each Underwriter might otherwise have.

c. Any party that proposes to assert the right to be indemnified under this Section 6 shall, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 6, notify each such indemnifying party in writing of the commencement of such action, enclosing with such notice a copy of all papers served, but the omission so to notify such indemnifying party will not relieve it from any liability that it may have to any indemnified party under the foregoing provisions of this Section 6 unless, and only to the extent that, such omission results in the loss of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party. After notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified

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party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (i) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (ii) there are legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (iii) the indemnified party has reasonably concluded that a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party), or (iv) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred. Any indemnifying party will not be liable for any settlement of any action or claim effected without its written consent (which consent will not be unreasonably withheld or delayed).

d. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 6 is applicable in accordance with its terms, but for any reason is held to be unavailable from the Company or the Underwriters, the indemnifying party will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than the Underwriters, such as persons who control the Company within the meaning of the Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and any one or more of the Underwriters may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company and the Underwriters. The relative benefits received by the Company and the Underwriters shall be deemed to be in the same proportion

as the total net proceeds from the offering (before deducting expenses) received by the Company bears to the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence, but also the relative fault of the Company and the Underwriters with respect to the statements or omissions which resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 6(d) were to be determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense or damage, or action in respect thereof, referred to above in this Section 6(d) shall be deemed to include, for purpose of this Section 6(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 6(d), no Underwriter shall be required to contribute any amount in excess of the underwriting discounts received by it and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations to contribute as provided in this Section 6(d) are several in proportion to their respective underwriting obligations and not joint. For purposes of this Section 6(d), any person who controls a party to this Agreement within the meaning of the Act will have the same rights to contribution as that party, and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against any such party in respect of which a claim for contribution may be made under this Section 6(d), will notify any such party or

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parties from whom contribution may be sought from any other obligation it or they may have under this Section 6(d). No party will be liable for contribution with respect to any action or claim settled without its written consent (which consent will not be unreasonably withheld or delayed).

e. The indemnity and contribution agreements contained in this Section 6 and the representations and warranties of the Company contained in this Agreement shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of the Underwriters, (ii) acceptance of any of the Shares and payment therefor, or (iii) any termination of this Agreement

#### 7. REIMBURSEMENT OF CERTAIN EXPENSES

In addition to its other obligations under Section 6(a) of this Agreement, the Company hereby agrees to reimburse the Underwriters on a quarterly basis for all reasonable legal and other expenses incurred in connection with investigating or defending any claim, action, investigation, inquiry or other proceeding arising out of or based upon in whole or part, (i) as described in Section 6(a), any untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, the Registration Statement or the Prospectus or any amendment or supplement to the Registration Statement or the Prospectus, or the omission or alleged omission to state in such document a material fact required to be stated in it or necessary to make the statements in it not misleading, (ii) any inaccuracy in the representations and warranties of the Company contained herein, or (iii) any failure of the Company to perform its obligations hereunder or under law in connection with the transactions contemplated hereby, notwithstanding the absence of a judicial determination as to the propriety and enforceability of the obligations under this Section 7 and the possibility that such payment might later be held to be improper; provided, however, that, to the extent any such payment is ultimately held to be improper, the persons receiving such payments shall promptly refund them

#### 8. TERMINATION

The obligations of the several Underwriters under this Agreement may be terminated at any time on or prior to the Closing Date (or, with respect to the Option Shares, on or prior to the Option Closing Date), by notice to the Company from the Underwriters, without liability on the part of any Underwriter to the

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Company if, prior to delivery and payment for the Firm Shares or Option Shares, as the case may be, in the sole judgment of the Underwriters, (a) trading in any of the equity securities of the Company shall have been suspended by the Commission or by the Nasdaq National Market, (b) trading in securities generally on the New York Stock Exchange or the Nasdaq National Market shall have been suspended or limited or minimum or maximum prices shall have been generally established on such exchange, or additional material governmental restrictions, not in force on the date of this Agreement, shall have been imposed upon trading in securities generally by such exchange or by order of the Commission or any court or other governmental authority, (c) a general banking moratorium shall have been declared by either Federal or New York State authorities, (d) any material adverse change in the financial or securities markets in the United States, or in political, financial or economic conditions in the United States or any outbreak or material escalation of hostilities or other calamity or crises, shall have occurred, the effect of which is such as to make it, in the sole judgment of the Underwriters, impracticable to market the Shares, (e) there has been a material adverse change since the respective dates as of which information is given in the Registration Statement and the Prospectus in the general affairs, business, business prospects, properties, management, condition (financial or otherwise), net worth or results of operations of the Company or any Subsidiary, whether or not arising from transactions in the ordinary course of business, in each case other than as described in or contemplated by the Registration Statement and the Prospectus, or (f) the Company or any Subsidiary has sustained any material loss or interference with its business or properties from fire, explosion, flood, earthquake or other casualty, whether or not covered by insurance, or from any labor dispute or any court or legislative or other government action, order or decree, which is not described in the Registration Statement and the Prospectus, if in the judgment of the Underwriters any such development makes it impracticable or inadvisable to consummate the sale and delivery of the Shares by the Underwriters at the public offering price.

## 9. SUBSTITUTION OF UNDERWRITERS

If any one or more of the Underwriters shall fail or refuse to purchase the Shares which it or they have agreed to purchase hereunder, and the aggregate number of Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase is not more than one-tenth of the aggregate number of Shares, the other Underwriters shall be obligated, severally, to purchase the

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Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase, in the proportions which the number of Shares which they have respectively agreed to purchase pursuant to Section 1 bears to the aggregate number of Shares which all such nondefaulting Underwriters have so agreed to purchase, or in such other proportions as the Underwriters may specify, provided that in no event shall the maximum number of Shares which any Underwriter has become obligated to purchase pursuant to Section 1 be increased pursuant to this Section 9 by more than one-ninth of such number of Shares without the prior written consent of such Underwriter. If any Underwriter or Underwriters shall fail or refuse to purchase any Shares and the aggregate number of Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase exceeds one-tenth of the aggregate number of the Shares and arrangements satisfactory to the Underwriters and the Company for the purchase of such Shares are not made within 48 hours after such default, this Agreement will terminate without liability on the part of any nondefaulting Underwriter or the Company for the purchase or sale of any Shares under this Agreement. In any such case which does not result in termination of this Agreement, either the Underwriters or the Company shall have the right to postpone the Closing Date, but in no event for longer than seven days, in order that the required changes, if any, in the Registration Statement and the Prospectus or in any other documents or arrangements may be effected. Any action taken pursuant to this Section 9 shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

## 10. MISCELLANEOUS

Notice given pursuant to any of the provisions of this Agreement shall be in writing and, unless otherwise specified, shall be mailed or delivered (a) if to the Company, at the offices of the Company, 375 West Street, West Bridgewater, Massachusetts 02379,, Attention: President, with a copy to Steven R. London, Esq., Brown, Rudnick, Freed & Gesmer, One Financial Center, Boston, Massachusetts 02111, and (b) if to the Underwriters, c/o Oscar Gruss & Son Incorporated, 74 Broad Street, New York, New York 10004, Attention: Stephen McGrath, Managing Director, with a copy to Paul Jacobs, Esq., Fulbright & Jaworski L.L.P., 666 Fifth Avenue, New York, New York 10103. Any such notice shall be effective only upon receipt. Any notice may be made by telex or telephone, but if so made shall be subsequently confirmed in writing.

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This Agreement has been and is made solely for the benefit of the several Underwriters, the Company and the controlling persons, directors and officers referred to in Section 6, and their respective successors and assigns, and no other person shall acquire or have any right under or by virtue of this Agreement. The term "SUCCESSORS AND ASSIGNS" as used in this Agreement shall not include a purchaser, as such, of Shares from any of the several Underwriters.

This Agreement shall be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed entirely within such State.

This Agreement may not be amended or modified except in a writing signed by both parties.

This Agreement may be signed in two or more counterparts with the same effect as if the signatures thereto and hereto were upon the same instrument.

In case any provision in this Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

Please confirm that the foregoing correctly sets forth the Agreement

_	

Very truly yours,

BOSTON BIOMEDICA, INC.

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

The foregoing Agreement is hereby confirmed and accepted as of the date first above written on behalf of themselves and the other several Underwriters named in Schedule I hereto.

KAUFMAN BROS., L.P. As Representatives of the several Underwriters

By: OSCAR GRUSS & SON INCORPORATED

Title:

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# SCHEDULE I SCHEDULE OF UNDERWRITERS

NUMBER OF FIRM SHARES

UNDERWRITERS TO BE PURCHASED

Total
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EXHIBIT A
[REPRESENTATIVES' WARRANT]
WARRANT
THIS WARRANT AND ANY SHARES ACQUIRED UPON THE EXERCISE OF THIS WARRANT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE SOLD OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT FILED UNDER SUCH ACT OR PURSUANT TO AN EXEMPTION FROM REGISTRATION UNDER SUCH ACT.
VOID AFTER 5:00 P.M., NEW YORK TIME, ON [insert date of fifth anniversary of closing], 2001, OR IF NOT A BUSINESS DAY, AS DEFINED HEREIN, AT 5:00 P.M., NEW YORK TIME, ON THE NEXT FOLLOWING BUSINESS DAY.
WARRANT TO PURCHASE
[]
SHARES OF COMMON STOCK
OF
BOSTON BIOMEDICA, INC.

No. W-\_\_\_

This certifies that, for and in consideration of services rendered and in connection with the initial public offering of Common Stock of the Company named below (the "OFFERING") and other good and valuable consideration, [Oscar Gruss & Son Incorporated/Kaufman Bros., L.P.] and its registered, permitted assigns (collectively, the "WARRANTHOLDER"), is entitled to purchase from Boston Biomedica, Inc., a corporation incorporated under the laws of the Commonwealth of Massachusetts (the "COMPANY"), subject to the terms and conditions hereof, at any time on or after 9:00 a.m., New York time, on [insert date of closing]

1997 and before 5:00 p.i	n., New York time on [insert date of fifth anniversary at
closing]	, 2001 (or, if such day is not a Business Day, at or
before 5:00 p.m., New Y	York time, on the next following Business Day), up to
160,000 fully paid and	nonassessable shares of Common Stock of the Company at
the Exercise Price (as de	efined herein). The Exercise Price and the number of
shares purchasable here	eunder are subject to adjustment from time to time as
provided in Article 3 her	reof.

#### ARTICLE 1

#### **DEFINITION OF TERMS**

As used in this Warrant, the following capitalized terms shall have the following respective meanings:

- (a) Business Day: A day other than a Saturday, Sunday or other day on which banks in the State of New York are authorized by law to remain closed.
- (b) Common Stock: Common Stock, \$.01 par value per share, of the Company.
- (c) Common Stock Equivalents: Securities that are convertible into or exercisable for shares of Common Stock.
  - (d) Demand Registration: See Section 6.2.
  - (e) Exchange Act: The Securities Exchange Act of 1934, as amended.
- (f) Exercise Price: \$\_\_\_ per Warrant Share, equal to 135% of the initial price to public in the offering as set forth on the cover page of the prospectus, dated \_\_\_\_, 1996, with respect to the initial public offering of the Company's Common Stock, as such price may be adjusted from time to time pursuant to Article 3 hereof.
- (g) Expiration Date: 5:00 p.m., New York time, on [fifth anniversary of closing] \_\_\_\_\_\_, 2001, or if such day is not a Business Day, the next succeeding day which is a Business Day.
  - (h) Holder: A Holder of Registrable Securities.

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- (i) NASD: National Association of Securities Dealers, Inc.
- (j) Net Issuance Exercise Date: See Section 2.3.
- (k) Net Issuance Right: See Section 2.3.
- (1) Net Issuance Warrant Shares: See Section 2.3.
- (m) Person: An individual, partnership, joint venture, corporation, trust, unincorporated organization or government or any department or agency thereof.
  - (n) Piggyback Registration: See Section 6.1.
- (o) Prospectus: Any prospectus included in any Registration Statement, as amended or supplemented by any prospectus supplement, or to which a Term Sheet (as defined in Rule 434 under the Securities Act) relates, with respect to the terms of the offering of any portion of the Registrable Securities covered by such Registration Statement and all other amendments and supplements to the Prospectus, including post-effective amendments and all materials incorporated by reference in such Prospectus.
- (p) Public Offering: A public offering of any of the Company's equity or debt securities pursuant to Registration Statement under the Securities Act.

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- (r) Registration Expenses: Any and all expenses incurred in connection with any registration or action incident to performance of or compliance by the Company with Article 6, including, without limitation, (i) all SEC, national securities exchange and NASD registration and filing fees; all listing fees and all transfer agent fees; (ii) all fees and expenses of complying with state securities or blue sky laws (including the fees and disbursements of counsel of the underwriters in connection with blue sky qualifications of the Registrable Securities); (iii) all printing, mailing, messenger and delivery expenses; (iv) all fees and disbursements of counsel for the Company and of its accountants, including the expenses of any special audits and/or "cold comfort" letters required by or incident to such performance and compliance; and (v) any disbursements of underwriters customarily paid by issuers or sellers of securities including the reasonable fees and expenses of any special experts retained by the underwriters in connection with the requested registration, but excluding underwriting discounts and commissions, brokerage fees and transfer taxes, if any, and fees of counsel or accountants retained by the holders of Registrable Securities to advise them in their capacity as Holders of Registrable Securities.
- (s) Registration Statement: Any registration statement of the Company filed or to be filed with the SEC which covers any of the Registrable Securities pursuant to the provisions of this Agreement, including all amendments (including post-effective amendments) and supplements thereto, all exhibits thereto and all material incorporated therein by reference.
- (t) SEC: The Securities and Exchange Commission or any other federal agency at the time administering the Securities Act and the Exchange Act.
  - (u) Securities Act: The Securities Act of 1933, as amended.
- (v) 25% Holders: At any time as to which a Demand Registration is requested, the Holder and/or the holders of any other Warrants and/or the holders of Warrant Shares who have the right to acquire or hold, as the case may be, not less than 25% of the combined total of Warrant Shares issuable and Warrant Shares outstanding (other than Warrant Shares which are no longer Registrable Securities by reason of the proviso to the definition of the term "Registrable Securities") at the time such Demand Registration is requested.

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- (w) Warrant Shares: Common Stock, Common Stock Equivalents and other securities purchased or purchasable upon exercise or conversion of the Warrants.
- (x) Warrantholder: The person(s) or entity(ies) to whom this Warrant is originally issued, or any successor in interest thereto, or any assignee or

transferee thereof, in whose name this Warrant is registered upon the books to be maintained by the Company for that purpose.

(y) Warrants: This Warrant, all other warrants issued on the date hereof and all other warrants that may be issued in its or their place (together evidencing the right to purchase an aggregate of up to 160,000 shares of Common Stock), originally issued as set forth in the definition of Registrable Securities.

#### ARTICLE 2

#### DURATION AND EXERCISE OF WARRANT

#### 2.1 DURATION OF WARRANT

The Warrantholder may exercise this Warrant at any time and from time to time after 9:00 a.m., New York time, on \_\_\_\_\_\_\_\_, 1997 [one year after the date of closing] and before 5:00 p.m., New York time, on the Expiration Date. If this Warrant is not exercised on the Expiration Date, it shall become void, and all rights hereunder shall thereupon cease.

#### 2.2 METHOD OF EXERCISE

- (a) The Warrantholder may exercise this Warrant, in whole or in part, by presentation and surrender of this Warrant to the Company at its corporate office at 375 West Street, West Bridgewater, Massachusetts 62379, or at the office of its stock transfer agent, if any, with the Exercise Form annexed hereto duly executed and, in the event of an exercise for cash pursuant to Section 2.3(a), accompanied by payment of the full Exercise Price for each Warrant Share to be purchased.
- (b) Upon receipt of this Warrant with the Exercise Form fully executed and, in the event of an exercise for cash pursuant to Section 2.3(a),

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accompanied by payment of the aggregate Exercise Price for the Warrant Shares for which this Warrant is then being exercised, the Company shall cause to be issued certificates for the total number of whole shares of Common Stock for which this Warrant is being exercised (adjusted to reflect the effect of the anti-dilution provisions contained in Article 3 hereof, if any, and as provided in Section 2.4 hereof) in such denominations as are requested for delivery to the Warrantholder, and the Company shall thereupon deliver such certificates to the Warrantholder. A net issuance exercise pursuant to Section 2.3(b) shall be effective upon receipt by the Company of this Warrant together with the aforesaid written statement, or on such later date as is specified therein (the "NET ISSUANCE EXERCISE DATE"), and, at the election of the Holder hereof, may be made contingent upon the closing of the sale of the Warrant Shares in a Public Offering. The Warrantholder shall be deemed to be the holder of record of the shares of Common Stock issuable upon such exercise as of the time of receipt of the Exercise Form and payment in accordance with the preceding sentence, in the case of an exercise for cash pursuant to Section 2.3(a), or as of the Net Issuance Exercise Date, in the case of a net issuance exercise pursuant to Section 2.3(b), notwithstanding that the stock transfer books of the Company shall then be closed or that certificates representing such shares of Common Stock shall not then be actually delivered to the Warrantholder. If at the time this Warrant is exercised, a Registration Statement is not in effect to register under the Securities Act the Warrant Shares issuable upon exercise of this Warrant, the Company may, in the case of an exercise for cash pursuant to Section 2.3(a) or in the case of a net issuance exercise prior to the satisfaction of any holding period required by Rule 144 promulgated under the Securities Act, require the Warrantholder to make such representations, and may place the legends on certificates representing the Warrant Shares, as may be reasonably required in the opinion of counsel to the Company to permit the Warrant Shares to be issued without such registration.

(c) In case the Warrantholder shall exercise this Warrant with respect to less than all of the Warrant Shares that may be purchased under this

Warrant, the Company shall execute as of the exercise date (or, if later, the Net Issuance Exercise Date) a new warrant in the form of this Warrant for the balance of such Warrant Shares and deliver such new warrant to the Warrantholder within 10 days following the exercise date (or, if later, the Net Issuance Exercise Date).

(d) The Company shall pay any and all stock transfer and similar taxes which may be payable in respect of the issuance of any Warrant Shares.

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#### 2.3 EXERCISE OF WARRANT

(a) Right to Exercise for Cash. This Warrant may be exercised by the Holder by delivery of payment to the Company, for the account of the Company, by cash, by certified or bank cashier's check or by wire transfer, of the Exercise Price for the number of Warrant Shares specified in the Exercise Form in lawful money of the United States of America.

(b) Right to Exercise on a Net Issuance Basis. In lieu of exercising this Warrant for cash pursuant to Section 2.3(a), the Holder shall have the right to exercise this Warrant or any portion thereof (the "NET ISSUANCE RIGHT") into shares of Common Stock as provided in this Section 2.3(b) at any time or from time to time during the period specified in Section 2.1 hereof by the surrender of this Warrant to the Company with a duly executed and completed Exercise Form marked to reflect net issuance exercise. Upon exercise of the Net Issuance Right with respect to a particular number of shares subject to this Warrant and noted on the Exercise Form (the "NET ISSUANCE WARRANT SHARES"), the Company shall deliver to the Holder (without payment by the Holder of any Exercise Price or any cash or other consideration) (X) that number of shares of fully paid and nonassessable Common Stock equal to the quotient obtained by dividing the value of this Warrant (or the specified portion hereof) on the Net Issuance Exercise Date, which value shall be determined by subtracting (A) the aggregate Exercise Price of the Net Issuance Warrant Shares immediately prior to the exercise of the Net Issuance Right from (B) the aggregate fair market value of the Net Issuance Warrant Shares issuable upon exercise of this Warrant (or the specified portion hereof) on the Net Issuance Exercise Date (as herein defined) by (Y) the fair market value of one share of Common Stock on the Net Issuance Exercise Date (as herein defined).

Expressed as a formula, such net issuance exercise shall be computed as follows:

$$X = B-A$$
 $Y$ 

Where: X = the number of shares of Common Stock that may be issued to the Holder

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- Y = the fair market value ("FMV") of one share of Common Stock as of the Net Issuance Exercise Date
- A = the aggregate Exercise Price (i.e., the product determined by multiplying the Net Issuance Warrant Shares by the Exercise Price)
- B = the aggregate FMV (i.e., the product determined by

multiplying the FMV by the Net Issuance Warrant Shares)

- (c) Determination of Fair Market Value. For purposes of this Section 2.3, "FAIR MARKET VALUE" of a share of Common Stock as of the Net Issuance Exercise Date shall mean:
- (i) if the Net Issuance Right is exercised in connection with and contingent upon a Public Offering, and if the Company's Registration Statement relating to such Public Offering has been declared effective by the SEC, then the initial "Price to Public" specified in the final Prospectus with respect to such offering.
- (ii) if the Net Issuance Right is not exercised in connection with and contingent upon a Public Offering, then as follows:
  - (A) If traded on a securities exchange, the fair market value of the Common Stock shall be deemed to be the average of the closing prices of the Common Stock on such exchange over the 30-day period ending five business days prior to the Net Issuance Exercise Date:
  - (B) If traded on the Nasdaq National Market or the Nasdaq SmallCap Market, the fair market value of the Common Stock shall be deemed to be the average of the last reported sales prices of the Common Stock on such Market over the 30-day period ending five business days prior to the Net Issuance Exercise Date;
  - (C) If traded over-the-counter other than on the Nasdaq National Market or the Nasdaq SmallCap Market, the fair market value of the Common Stock shall be deemed to be the average of the closing bid

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prices of the Common Stock over the 30-day period ending five business days prior to the Net Issuance Exercise Date; and

(D) If there is no public market for the Common Stock, then fair market value shall be determined by mutual agreement of the Warrantholder and the Company, and if the Warrantholder and the Company are unable to so agree, at the Company's sole expense, by an investment banker of national reputation selected by the Company and reasonably acceptable to the Warrantholder.

## 2.4 RESERVATION OF SHARES

The Company hereby agrees that at all times there shall be reserved for issuance and delivery upon exercise of this Warrant such number of shares of Common Stock or other shares of capital stock of the Company from time to time issuable upon exercise of this Warrant. All such shares shall be duly authorized, and when issued upon such exercise, shall be validly issued, fully paid and non-assessable, free and clear of all liens, security interests, charges and other encumbrances or restrictions on sale (except as contemplated by Sections 2.2(b) and 5.2) and free and clear of all preemptive and other similar rights.

# 2.5 FRACTIONAL SHARES

The Company shall not be required to issue any fraction of a share of its capital stock in connection with the exercise of this Warrant, and in any case where the Warrantholder would, except for the provisions of this Section 2.5, be entitled under the terms of this Warrant to receive a fraction of a share upon the exercise of this Warrant, the Company shall, upon the exercise of this Warrant, pay to the Warrantholder an amount in cash equal to the fair market value of such fractional share as of the exercise date (or, if applicable and a later date, the Net Issuance Exercise Date).

Prior to the issuance of any shares of Common Stock upon exercise of this Warrant, the Company shall secure the listing of such shares of Common Stock upon each national securities exchange or automated quotation system, if any, upon which shares of Common Stock are then listed (subject to official notice of

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issuance upon exercise of this Warrant) and shall maintain, so long as any other shares of Common Stock shall be so listed, such listing of all shares of Common Stock from time to time issuable upon the exercise of this Warrant; and the Company shall so list on each national securities exchange or automated quotation system, and shall maintain such listing of, any other shares of capital stock of the Company issuable upon the exercise of this Warrant if and so long as any shares of the same class shall be listed on such national securities exchange or automated quotation system.

#### ARTICLE 3

# ADJUSTMENT OF SHARES OF COMMON STOCK PURCHASABLE AND OF EXERCISE PRICE

The Exercise Price and the number and kind of Warrant Shares shall be subject to adjustment from time to time upon the happening of certain events as provided in this Article 3.

## 3.1 MECHANICAL ADJUSTMENTS

(a) If at any time prior to the exercise of this Warrant in full, the Company shall (i) declare a dividend or make a distribution on the Common Stock payable in shares of its capital stock (whether shares of Common Stock or of capital stock of any other class); (ii) subdivide, reclassify or recapitalize its outstanding Common Stock into a greater number of shares; (iii) combine, reclassify or recapitalize its outstanding Common Stock into a smaller number of shares; or (iv) issue any shares of its capital stock by reclassification of its Common Stock (including any such reclassification in connection with a consolidation or a merger in which the Company is the continuing corporation), the number of Warrant Shares issuable upon exercise of the Warrant and/or the Exercise Price in effect at the time of the record date of such dividend, distribution, subdivision, combination, reclassification or recapitalization shall be adjusted so that the Warrantholder shall be entitled to receive the aggregate number and kind of shares which, if this Warrant had been exercised in full immediately prior to such event, the Warrantholder would have owned upon such exercise and been entitled to receive by virtue of such dividend, distribution, subdivision, combination, reclassification or recapitalization. Any adjustment required by this Section 3.1(a) shall be made successively immediately after the record date, in the case of a

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dividend or distribution, or the effective date, in the case of a subdivision, combination, reclassification or recapitalization, to allow the purchase of such aggregate number and kind of shares.

(b) If any time prior to the exercise of this Warrant in full, the Company shall fix a record date for the issuance or making of a distribution to all holders of the Common Stock (including any such distribution to be made in connection with a consolidation or merger in which the Company is to be the continuing corporation) of evidences of its indebtedness, any other securities of the Company or any cash, property or other assets (excluding a combination, reclassification or recapitalization referred to in Section 3.1(a), regular cash dividends or cash distributions paid out of net profits legally available therefor and in the ordinary course of business if the full amount thereof,

together with the value of other dividends and distributions made substantially concurrently therewith or pursuant to a plan which includes payment thereof, is equivalent to not more than 5% of the Company's net worth, or subscription rights, options or warrants for Common Stock or Common Stock Equivalents (excluding those referred to in Section 3.1(b)) (any such nonexcluded event being herein called a "SPECIAL DIVIDEND")), the Exercise Price shall be decreased immediately after the record date for such Special Dividend to a price determined by multiplying the Exercise Price then in effect by a fraction, the numerator of which shall be the then current market price of the Common Stock (as defined in Section 3.1(e)) on such record date less the fair market value (as determined in good faith by the Board of Directors of the Company) of the evidences of indebtedness, securities or property, or other assets issued or distributed in such Special Dividend applicable to one share of Common Stock or of such subscription rights or warrants applicable to one share of Common Stock and the denominator of which shall be the then current market price per share of Common Stock (as so determined). Any adjustments required by this Section 3.1(b) shall be made successively whenever such a record date is fixed and in the event that such distribution is not so made, the Exercise Price shall again be adjusted to be the Exercise Price that was in effect immediately prior to such record date.

(c) If at any time prior to the exercise of this Warrant in full, the Company shall make a distribution to all holders of the Common Stock of stock of a subsidiary or securities convertible into or exercisable for such stock, then in lieu of an adjustment in the Exercise Price or the number of Warrant Shares purchasable upon the exercise of this Warrant, each Warrantholder, upon the exercise hereof

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at any time after such distribution, shall be entitled to receive from the Company, such subsidiary or both, as the Company shall determine, the stock or other securities to which such Warrantholder would have been entitled if such Warrantholder had exercised this Warrant immediately prior thereto, all subject to further adjustment as provided in this Article 3, and the Company shall reserve, for the life of the Warrant, such securities of such subsidiary or other corporation; provided, however, that no adjustment in respect of dividends or interest on such stock or other securities shall be made during the term of this Warrant or upon its exercise.

- (d) Whenever the Exercise Price payable upon exercise of each Warrant is adjusted pursuant to one or more of paragraphs (a) and (b) of this Section 3.1, the Warrant Shares shall simultaneously be adjusted by multiplying the number of Warrant Shares initially issuable upon exercise of each Warrant by the Exercise Price in effect on the date thereof and dividing the product so obtained by the Exercise Price, as adjusted.
- (e) For the purpose of any computation under this Section 3.1, the current market price per share of Common Stock at any date shall be deemed to be the average of the daily closing prices for 20 consecutive trading days commencing 30 trading days before such date. The closing price for each day shall be the last sale price regular way or, in case no such reported sales take place on such day, the average of the last reported bid and asked prices regular way, in either case on the principal national securities exchange on which the Common Stock is admitted to trading or listed, or if not listed or admitted to trading on such exchange, the representative closing bid price as reported by Nasdaq, or other similar organization if Nasdaq is no longer reporting such information, or if not so available, the fair market price as determined in good faith by the Board of Directors of the Company.
- (f) No adjustment in the Exercise Price shall be required unless such adjustment would require an increase or decrease of at least five cents (\$.05) in such price; provided, however, that any adjustments which by reason of this paragraph (f) are not required to be made shall be carried forward and taken into account in any subsequent adjustment. All calculations under this Section 3.1 shall be made to the nearest cent or to the nearest one-hundredth of a share, as the case may be. Notwithstanding anything in this Section 3.1 to the contrary, the

Exercise Price shall not be reduced to less than the then existing par value of the Common Stock as a result of any adjustment made hereunder.

- (g) In the event that at any time, as a result of any adjustment made pursuant to Section 3.1(a), the Warrantholder thereafter shall become entitled to receive any shares of the Company other than Common Stock, thereafter the number of such other shares so receivable upon exercise of any Warrant shall be subject to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the Common Stock contained in this Section 3.1.
- (h) In case any event shall occur as to which the other provisions of this Article 3 are not strictly applicable but as to which the failure to make any adjustment would not fairly protect the purchase rights represented by this Warrant in accordance with the essential intent and principles hereof then, in each such case, the Warrantholders representing the right to purchase a majority of the Warrant Shares subject to all outstanding Warrants may appoint a firm of independent public accountants of recognized national standing reasonably acceptable to the Company, which shall give their opinion as to the adjustment, if any, on a basis consistent with the essential intent and principles established herein, necessary to preserve the purchase rights represented by the Warrants. Upon receipt of such opinion, the Company will promptly mail a copy thereof to the Warrantholder and shall make the adjustments described therein. The fees and expenses of such independent public accountants shall be borne by the Company.
- (i) If, as a result of an adjustment made pursuant to this Article 3, the Holder of any Warrant thereafter surrendered for exercise shall become entitled to receive shares of two or more classes of capital stock or shares of Common Stock and other capital stock of the Company, the Board of Directors (whose determination shall be conclusive and shall be described in a written notice to the Holder of any Warrant promptly after such adjustment) shall determine the allocation of the adjusted Exercise Price between or among shares or such classes of capital stock or shares of Common Stock and other capital stock.

## 3.2 NOTICES OF ADJUSTMENT

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Whenever the number of Warrant Shares or the Exercise Price is adjusted as herein provided, the Company shall prepare and deliver forthwith to the Warrantholder a certificate signed by its President, and by any Vice President, Treasurer or Secretary, setting forth the adjusted number of shares purchasable upon the exercise of this Warrant and the Exercise Price of such shares after such adjustment, setting forth a brief statement of the facts requiring such adjustment and setting forth the computation by which adjustment was made.

# 3.3 NO ADJUSTMENT FOR DIVIDENDS

Except as provided in Section 3.1 of this Agreement, no adjustment in respect of any cash dividends shall be made during the term of this Warrant or upon the exercise of this Warrant.

## 3.4 PRESERVATION OF PURCHASE RIGHTS IN CERTAIN TRANSACTIONS

In case of any reclassification, capital reorganization or other change of outstanding shares of Common Stock (other than a subdivision or combination of the outstanding Common Stock and other than a change in the par value of the

Common Stock) or in case of any consolidation or merger of the Company with or into another corporation (other than merger with a subsidiary in which the Company is the continuing corporation and that does not result in any reclassification, capital reorganization or other change of outstanding shares of Common Stock of the class issuable upon exercise of this Warrant) or in the case of any sale, lease, transfer or conveyance to another corporation of the property and assets of the Company as an entirety or substantially as an entirety, the Holder of this Warrant shall have the right thereafter to receive on the exercise of this Warrant the kind and amount of securities, cash or other property which the Holder would have owned or have been entitled to receive immediately after such reorganization, reclassification, consolidation, merger, statutory exchange, sale or conveyance had this Warrant been exercised immediately prior to the effective date of such reorganization, reclassification, consolidation, merger, statutory exchange, sale or conveyance and in any such case, if necessary, appropriate adjustment shall be made in the application of the provisions set forth in this Article 3 with respect to the rights and interests thereafter of the Holder of this Warrant to the end that the provisions set forth in this Article 3 shall thereafter correspondingly be made applicable, as nearly as may reasonably be, in relation to any shares of stock or other securities or property thereafter deliverable on the exercise of

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Warrant. The provisions of this Section 3.4 shall similarly apply to successive reorganizations, reclassifications, consolidations, mergers, statutory exchanges, sales or conveyances. The issuer of any shares of stock or other securities or property thereafter deliverable on the exercise of this Warrant shall be responsible for all of the agreements and obligations of the Company hereunder. Notice of any such reorganization, reclassification, consolidation, merger, statutory exchange, sale or conveyance and of said provisions so proposed to be made, shall be mailed to the Holders of the Warrants not less than 30 days prior to such event. A sale of all or substantially all of the assets of the Company for a consideration consisting primarily of securities shall be deemed a consolidation or merger for the foregoing purposes.

## 3.5 FORM OF WARRANT AFTER ADJUSTMENTS

The form of this Warrant need not be changed because of any adjustments in the Exercise Price or the number or kind of the Warrant Shares, and Warrants theretofore or thereafter issued may continue to express the same price and number and kind of shares as are stated in this Warrant, as initially issued.

## 3.6 TREATMENT OF WARRANTHOLDER

Prior to due presentment for registration of transfer of this Warrant, the Company may deem and treat the Warrantholder as the absolute owner of this Warrant (notwithstanding any notation of ownership or other writing hereon) for all purposes and shall not be affected by any notice to the contrary.

# ARTICLE 4

## OTHER PROVISIONS RELATING TO RIGHTS OF WARRANTHOLDER

## 4.1 NO RIGHTS AS SHAREHOLDERS; NOTICE TO WARRANTHOLDERS

Nothing contained in this Warrant shall be construed as conferring upon the Warrantholder or his, her or its transferees the right to vote or to receive dividends or to consent or to receive notice as a shareholder in respect of any meeting of shareholders for the election of directors of the Company or of any other matter, or any rights whatsoever as shareholders of the Company. The Company shall give

notice to the Warrantholder by registered mail if at any time prior to the expiration or exercise in full of the Warrants, any of the following events shall occur:

- (a) the Company shall authorize the payment of any dividend payable in any securities upon shares of Common Stock or authorize the making of any distribution (other than a cash dividend subject to the parenthetical set forth in Section 3.1(b)) to all holders of Common Stock:
- (b) the Company shall authorize the issuance to all holders of Common Stock of any additional shares of Common Stock or Common Stock Equivalents or of rights, options or warrants to subscribe for or purchase Common Stock or Common Stock Equivalents or of any other subscription rights, options or warrants;
- (c) a dissolution, liquidation or winding up of the Company shall be proposed; or
- (d) a capital reorganization or reclassification of the Common Stock (other than a subdivision or combination of the outstanding Common Stock and other than a change in the par value of the Common Stock) or any consolidation or merger of the Company with or into another corporation (other than a consolidation or merger in which the Company is the continuing corporation and that does not result in any reclassification or change of Common Stock outstanding) or in the case of any sale or conveyance to another corporation of the property of the Company as an entirety or substantially as an entirety.

Such notice shall be given (i) at least 10 Business Days prior to the date fixed as a record date or effective date or the date of closing of the Company's stock transfer books for the determination of the shareholders entitled to such dividend, distribution or subscription rights, or for the determination of the shareholders entitled to vote on such proposed merger, consolidation, sale, conveyance, dissolution, liquidation or winding up. Such notice shall specify such record date or the date of closing the stock transfer books, as the case may be. Failure to provide such notice shall not affect the validity of any action taken in connection with such dividend, distribution or subscription rights, or proposed merger, consolidation, sale, conveyance, dissolution, liquidation or winding up.

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## 4.2 LOST, STOLEN, MUTILATED OR DESTROYED WARRANTS

If this Warrant is lost, stolen, mutilated or destroyed, the Company may, on such terms as to indemnity or otherwise as it may in its reasonable judgment impose (which shall, in the case of a mutilated Warrant, include the surrender thereof), issue a new Warrant of like denomination and tenor as, and in substitution for, this Warrant.

# ARTICLE 5

# SPLIT-UP, COMBINATION, EXCHANGE AND TRANSFER OF WARRANTS AND WARRANT SHARES

# 5.1 SPLIT-UP, COMBINATION AND EXCHANGE OF WARRANTS

This Warrant may be split up, combined or exchanged for another Warrant or Warrants containing the same terms to purchase a like aggregate number of Warrant Shares. If the Warrantholder desires to split up, combine or exchange this Warrant, he, she or it shall make such request in writing delivered to the Company and shall surrender to the Company this Warrant and any other Warrants to be so split up, combined or exchanged. Upon any such surrender for a split-up, combination or exchange, the Company shall execute and deliver to the person entitled thereto a Warrant or Warrants, as the case may be, as so requested. The Company shall not be required to effect any split-up, combination

or exchange which will result in the issuance of a Warrant entitling the Warrantholder to purchase upon exercise a fraction of a share of Common Stock or a fractional Warrant. The Company may require such Warrantholder to pay a sum sufficient to cover any tax or governmental charge that may be imposed in connection with any split-up, combination or exchange of Warrants.

## 5.2 RESTRICTIONS ON TRANSFER, RESTRICTIVE LEGENDS

Except as otherwise permitted by this Section 5.2, each Warrant shall (and each Warrant issued upon direct or indirect transfer or in substitution for any Warrant issued pursuant to Section 5.1 shall) be stamped or otherwise imprinted with a legend in substantially the following form:

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"THIS WARRANT AND ANY SHARES ACQUIRED UPON THE EXERCISE OF THIS WARRANT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE SOLD OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT FILED UNDER SUCH ACT OR PURSUANT TO AN EXEMPTION FROM REGISTRATION UNDER SUCH ACT."

Except as otherwise permitted by this Section 5.2, each stock certificate for Warrant Shares issued upon the exercise of any Warrant and each stock certificate issued upon the direct or indirect transfer of any such Warrant Shares shall be stamped or otherwise imprinted with a legend in substantially the following form:

"THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UWNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE SOLD OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT FILED UNDER SUCH ACT OR PURSUANT TO AN EXEMPTION FROM REGISTRATION UNDER SUCH ACT."

Notwithstanding the foregoing, the Warrantholder may require the Company to issue a Warrant or a stock certificate for Warrant Shares, in each case without a legend, if (i) the issuance of such Warrant Shares has been registered under the Securities Act, (ii) such Warrant or such Warrant Shares, as the case may be, have been registered for resale under the Securities Act or sold pursuant to Rule 144 under the Securities Act (or a successor thereto) or (iii) the Warrantholder has received an opinion of counsel (who may be house counsel for such Warrantholder) reasonably satisfactory to the Company that such registration is not required with respect to such Warrant or such Warrant Shares, as the case may be.

## ARTICLE 6

## REGISTRATION UNDER THE SECURITIES ACT OF 1933

## 6.1 PIGGYBACK REGISTRATION

(a) Right to Include Registrable Securities. If at any time or from time to time prior to the second anniversary of the Expiration Date, the Company proposes to register any of its securities under the Securities Act on any form for the registration of securities under such Act, whether or not for its own account (other

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than by a registration statement on Form S-8 or other form which does not include substantially the same information as would be required in a form for the general registration of securities or would not be available for the Registrable Securities) (a "PIGGYBACK REGISTRATION"), it shall as expeditiously as possible give written notice to all Holders of its intention to do so and of

such Holders' rights under this Section 6.1. Such rights are referred to hereinafter as "PIGGYBACK REGISTRATION RIGHTS." Upon the written request of any such Holder made within 20 days after receipt of any such notice (which request shall specify the Registrable Securities intended to be disposed of by such Holder), the Company shall include in the Registration Statement the Registrable Securities which the Company has been so requested to register by the Holders thereof and the Company shall keep such registration statement in effect and maintain compliance with each federal and state law or regulation for the period necessary for such Holder to effect the proposed sale or other disposition (but in no event for a period greater than 90 days).

- (b) Withdrawal of Piggyback Registration by Company. If, at any time after giving written notice of its intention to register any securities in a Piggyback Registration but prior to the effective date of the related Registration Statement, the Company shall determine for any reason not to register such securities, the Company shall give notice of such determination to each Holder and, thereupon, shall be relieved of its obligation to register any Registrable Securities in connection with such Piggyback Registration. All best efforts obligations of the Company pursuant to Section 6.4 shall cease if the Company determines to terminate prior to such effective date any registration where Registrable Securities are being registered pursuant to this Section 6.1.
- (c) Piggyback Registration of Underwritten Public Offering. If a Piggyback Registration involves an offering by or through underwriters, then (i) all Holders requesting to have their Registrable Securities included in the Company's Registration Statement must sell their Registrable Securities to the underwriters selected by the Company on the same terms and conditions as apply to other selling shareholders and (ii) any Holder requesting to have his, her or its Registrable Securities included in such Registration Statement may elect in writing, not later than three Business Days prior to the effectiveness of the Registration Statement filed in connection with such registration, not to have his or its Registrable Securities so included in connection with such registration.

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- (d) Payment of Registration Expenses for Piggyback Registration. The Company shall pay all Registration Expenses in connection with each registration of Registrable Securities requested pursuant to a Piggyback Registration Right contained in this Section 6.1.
- (e) Priority in Piggyback Registration. If a Piggyback Registration involves an offering by or through underwriters, the Company, except as otherwise provided herein, shall not be required to include Registrable Shares therein if and to the extent the underwriter managing the offering reasonably believes in good faith and advises each Holder requesting to have Registrable Securities included in the Company's Registration Statement that such inclusion would materially adversely affect such offering; provided, that (i) if other selling shareholders without contractual registration rights have requested registration of securities in the proposed offering, the Company will reduce or eliminate such securities held by selling shareholders without registration rights before any reduction or elimination of Registrable Securities; and (ii) any such reduction or elimination (after taking into account the effect of clause (i)) shall be pro rata to all other selling shareholders with contractual registration rights.

# 6.2 DEMAND REGISTRATION

(a) Request for Registration. If, at any time prior to the Expiration Date, any 25% Holders request that the Company file a registration statement under the Securities Act, as soon as practicable thereafter the Company shall use its best efforts to file a registration statement with respect to all Warrant Shares that it has been so requested to include and obtain the effectiveness thereof, and to take all other action necessary under federal or state law or regulation to permit the Warrant Shares that are held and/or that may be acquired upon the exercise of the Warrants specified in the notices of the Holders or holders hereof to be sold or otherwise disposed of, and the Company shall maintain such compliance with each such federal and state law and regulation for the period necessary for such Holders or holders to effect the

proposed sale or other disposition; provided, however, the Company shall be entitled to defer such registration for a period of up to 60 days if and to the extent that its Board of Directors shall determine in good faith that such registration would require disclosure of information not then otherwise required to be disclosed and that such disclosure would adversely affect any material business situation, transaction or negotiation then proposed, contemplated or being engaged in by the Company. The Company shall also

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promptly give written notice to the Holders and the holders of any other Warrants and/or the holders of any Warrant Shares who or that have not made a request to the Company pursuant to the provisions of this Section 6.2(a) of its intention to effect any required registration or qualification, and shall use its best efforts to effect as expeditiously as possible such registration or qualification of all such other Warrant Shares that are then held and/or that may be acquired upon the exercise of the Warrants, the Holders or holders of which have requested such registration or qualification, within 15 days after such notice has been given by the Company, as provided in the preceding sentence. The Company shall be required to effect a registration or qualification pursuant to this Section 6.2(a) on one occasion only.

- (b) Payment of Registration Expenses for Demand Registration. The Company shall pay all Registration Expenses in connection with the Demand Registration.
- (c) Selection of Underwriters. If any Demand Registration is requested to be in the form of an underwritten offering, the managing underwriter shall be Oscar Gruss & Son Incorporated and the co-manager (if any) and the independent price required under the rules of the NASD (if any) shall be selected and obtained by the Holders of a majority of the Warrant Shares to be registered. Such selection shall be subject to the Company's consent, which consent shall not be unreasonably withheld. All fees and expenses (other than Registration Expenses otherwise required to be paid) of any managing underwriter, any co-manager or any independent underwriter or other independent price required under the rules of the NASD shall be paid for by such underwriters or by the Holders or holders whose shares are being registered. If Oscar Gruss & Son Incorporated should decline to serve as managing underwriter, the Holders of a majority of the Warrant Shares to be registered may select and obtain one or more managing underwriters. Such selection shall be subject to the Company's consent, which shall not be unreasonably withheld.
- (d) Procedure for Requesting Demand Registration. Any request for a Demand Registration shall specify the aggregate number of the Registrable Securities proposed to be sold and the intended method of disposition. Within 10 days after receipt of such a request the Company will give written notice of such registration request to all Holders, and, subject to the limitations of Section 6.2(b), the Company will include in such registration all Registrable Securities with respect to which the Company has received written requests for inclusion therein within 15

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Business Days after the date on which such notice is given. Each such request shall also specify the aggregate number of Registrable Securities to be registered and the intended method of disposition thereof.

## 6.3 BUY-OUTS OF REGISTRATION DEMAND

In lieu of carrying out its obligations to effect a Piggyback Registration or Demand Registration of any Registrable Securities pursuant to this Article 6, the Company may carry out such obligation by offering to purchase and purchasing such Registrable Securities requested to be registered in an amount in cash equal to the difference between (a) 95% of the last sale price of the Common Stock on the day the request for registration is made and (b) the Exercise Price in effect on such day; provided, however, that the Holder or Holders may withdraw such request for registration rather than accept such offer by the Company.

#### 6.4 REGISTRATION PROCEDURES

If and whenever the Company is required to use its best efforts to take action pursuant to any Federal or state law or regulation to permit the sale or other disposition of any Registrable Securities that are then held or that may be acquired upon exercise of the Warrants in order to effect or cause the registration of any Registrable Securities under the Securities Act as provided in this Article 6, the Company shall, as expeditiously as practicable:

(a) prepare and file with the SEC, as soon as practicable within 60 days after the end of the period within which requests for registration may be given to the Company (but subject to the provision for deferral contained in Section 6.2(a) hereof) a Registration Statement or Registration Statements relating to the registration on any appropriate form under the Securities Act, which form shall be available for the sale of the Registrable Securities in accordance with the intended method or methods of distribution thereof, and use its best efforts to cause such Registration Statements to become effective; provided, that before filing a Registration Statement or Prospectus or any amendment or supplements thereto, including documents incorporated by reference after the initial filing of any Registration Statement, the Company will furnish to the Holders of the Registrable Securities covered by such Registration Statement and the underwriters, if any, copies of all such documents proposed to be filed, which documents will be subject to the review of such Holders and underwriters;

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(b) prepare and file with the SEC such amendments and post-effective amendments to a Registration Statement as may be necessary to keep such Registration Statement effective for 180 days if the offering is not underwritten, provided, that such 180 day period shall be extended by the number of days a Prospectus is not available pursuant to Section 6.4(k) because of the occurrence of an event set forth in Section 6.4(c)(vi); cause the related Prospectus to be supplemented by any required Prospectus supplement, and as so supplemented to be filed pursuant to Rule 424 under the Securities Act; and comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such Registration Statement during such period in accordance with the intended methods of disposition by the sellers thereof set forth in such Registration Statement or supplement to such Prospectus;

(c) notify the selling Holders of Registrable Securities and the managing underwriters, if any, promptly, and (if requested by any such Person) confirm such advice in writing, (i) when a Prospectus or any Prospectus supplement or post-effective amendment has been filed, and, with respect to a Registration Statement or any post-effective amendment, when the same has become effective; (ii) of any request by the SEC for amendments or supplements to a Registration Statement or related Prospectus or for additional information; (iii) of the issuance by the SEC of any stop order suspending the effectiveness of a Registration Statement or the initiation of any proceedings for that purpose; (iv) if at any time the representations and warranties of the Company contemplated by paragraph (m) below ceases to be true and correct in all material respects; (v) of the receipt by the Company of any notification with respect to the suspension of the qualification of any of the Registrable Securities for sale in any jurisdiction or the initiation or threatening of any proceeding for such purposes; and (vi) of the happening of any event that makes any statement of a material fact made in the Registration Statement, the Prospectus or any document incorporated therein by reference untrue or which requires the making of any changes in the Registration Statement or Prospectus so that they will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading:

(d) make every reasonable effort to obtain the withdrawal of any order suspending the effectiveness of a Registration Statement at the earliest possible moment;

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- (e) if reasonably requested by the managing underwriters, immediately incorporate in a Prospectus supplement or post-effective amendment such information as the managing underwriters believe (on advice of counsel) should be included therein as required by applicable law relating to such sale of Registrable Securities, including, without limitation, information with respect to the purchase price being paid for the Registrable Securities by such underwriters and with respect to any other terms of the underwritten (or "best-efforts" underwritten) offering; and make all required filings of such Prospectus supplement or post-effective amendment as soon as notified of the matters to be incorporated in such Prospectus supplement or post-effective amendment;
- (f) furnish to each selling Holder of Registrable Securities and each managing underwriter, without charge, at least one signed copy of the Registration Statement and any post-effective amendment thereto, including financial statements and schedules, all documents incorporated therein by reference and all exhibits (including those incorporated by reference);
- (g) deliver to each selling Holder of Registrable Securities and the underwriters, if any, without charge, as many copies of the Prospectus or Prospectuses (including each preliminary prospectus) any amendment or supplement thereto as such Persons may reasonably request; the Company consents to the use of such Prospectus or any amendment or supplement thereto by each of the selling Holders of Registrable Securities and the underwriters, if any, in connection with the offering and sale of the Registrable Securities covered by such Prospectus or any amendment or supplement thereto;
- (h) prior to any public offering of Registrable Securities, cooperate with the selling Holders of Registrable Securities, the underwriters, if any, and their respective counsel in connection with the registration or qualification of such Registrable Securities for offer and sale under the securities or Blue Sky laws of such jurisdictions within the United States as any selling Holder or underwriter reasonably requests in writing, keep each such registration or qualification effective during the period such Registration Statement is required to be kept effective and do any and all other acts or things necessary or advisable to enable the disposition in such jurisdictions of the Registrable Securities covered by the applicable Registration Statement; provided that the Company will not be required to qualify to do business in any jurisdiction where it not then so qualified or to take any action which would subject the Company to general service of process in any jurisdiction where it is not at the time so subject;

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- (i) cooperate with the selling Holders of Registrable Securities and the managing underwriters, if any, to facilitate the timely preparation and delivery of certificates representing Registrable Securities to be sold and not bearing any restrictive legends; and enable such Registrable Securities to be in such denominations and registered in such names as the managing underwriters may request at least two Business Days prior to any sale of Registrable Securities to the underwriters;
- (j) use its best efforts to cause the Registrable Securities covered by the applicable Registration Statement to be registered with or approved by such other governmental agencies or authorities within the United

States as may be necessary to enable the seller or sellers thereof or the underwriters, if any, to consummate the disposition of such Registrable Securities:

- (k) upon the occurrence of any event contemplated by Section 6.4(c)(vi) above, prepare a supplement or post-effective amendment to the applicable Registration Statement or related Prospectus or any document incorporated therein by reference or file any other required document so that, as thereafter delivered to the purchasers of the Registrable Securities being sold thereunder, such Prospectus will not contain an untrue statement of a material fact or omit to state any material fact necessary to make the statements therein not misleading;
- (l) with respect to each issue or class of Registrable Securities, use its best efforts to cause all Registrable Securities covered by the Registration Statements to be listed on each securities exchange or automated quotation system, if any, on which similar securities issued by the Company are then listed if requested by the Holders of a majority of such issue or class of Registrable Securities;
- (m) enter into such agreements (including an underwriting agreement) and take all such other action reasonably required in connection therewith in order to expedite or facilitate the disposition of such Registrable Securities and in such connection, if the registration is in connection with an underwritten offering (i) make such representations and warranties to the underwriters (or the Holders of the Registrable Securities if such offering is not underwritten), in such form, substance and scope as are customarily made by issuers to underwriters in underwritten offerings and confirm the same if and when requested; (ii) obtain opinions of counsel to the Company and updates thereof

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(which counsel and opinions in form, scope and substance shall be reasonably satisfactory to the underwriters) addressed to the underwriters (or the Holders of the Registrable Securities if such offering is not underwritten) covering the matters customarily covered in opinions requested in underwritten offerings and such other matters as may be reasonably requested by such underwriters (or the Holders of the Registrable Securities if such offering is not underwritten); (iii) obtain "cold comfort" letters and updates thereof from the Company's accountants addressed to the underwriters (or the Holders of the Registrable Securities if such offering is not underwritten), such letters to be in customary form and covering matters of the type customarily covered in "cold comfort" letters by underwriters in connection with underwritten offerings; (iv) set forth in full in any underwriting agreement entered into the indemnification provisions and procedures of Section 6.5 hereof with respect to all parties to be indemnified pursuant to said Section; and (v) deliver such documents and certificates as may be reasonably requested by the underwriters to evidence compliance with clause (i) above and with any customary conditions contained in the underwriting agreement or other agreement entered into by the Company; the above shall be done at each closing under such underwriting or similar agreement or as and to the extent required hereunder;

- (n) make available for inspection by one or more representatives of the Holders of Registrable Securities being sold, any underwriter participating in any disposition pursuant to such registration, and any attorney or accountant retained by such Holders or underwriter, all financial and other records, pertinent corporate documents and properties of the Company, and cause the Company's officers, directors and employees to supply all information reasonably requested by any such representatives, in connection with such; and
- (o) otherwise use its best efforts to comply with all applicable Federal and state regulations; and take such other action as may be reasonably necessary to or advisable to enable each such Holder and each such underwriter to consummate the sale or disposition in such jurisdiction or jurisdiction in which any such Holder or underwriter shall have requested that

the Registrable Securities be sold.

Except as otherwise provided in this Agreement, the Company shall have sole control in connection with the preparation, filing, withdrawal, amendment or supplementing of each Registration Statement, the selection of underwriters, and

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the distribution of any preliminary prospectus included in the Registration Statement, and may include within the coverage thereof additional shares of Common Stock or other securities for its own account or for the account of one or more of its other security holders.

The Company may require each Seller of Registrable Securities as to which any registration is being effected to furnish to the Company such information regarding the distribution of such securities and such other information as may otherwise be required by the Securities Act to be included in such Registration Statement.

#### 6.5 INDEMNIFICATION

(a) Indemnification by Company. In connection with each Registration Statement relating to disposition of Registrable Securities, the Company shall indemnify and hold harmless each Holder, its officers, directors and agents and each underwriter of Registrable Securities and each Person, if any, who controls such Holder or underwriter (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) against any and all losses, claims, damages and liabilities, joint or several (including any reasonable investigation, legal and other expenses incurred in connection with, and any amount paid in settlement of any action, suit or proceeding or any claim asserted), to which they, or any of them, may become subject under the Securities Act, the Exchange Act or other federal or state law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in any Registration Statement, Prospectus or preliminary prospectus or any amendment thereof or supplement thereto, or arise out of or are based upon any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that such indemnity shall not inure to the benefit of any Holder or underwriter (or any Person controlling such Holder or underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) on account of any losses, claims, damages or liabilities arising from the sale of the Registrable Securities if such untrue statement or omission or alleged untrue statement or omission was made in such Registration Statement, Prospectus or preliminary prospectus, or such amendment or supplement, in reliance upon and in conformity with information furnished in writing to the Company by such Holder or underwriter specifically for

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use therein. The Company shall also indemnify selling brokers, dealer managers and similar securities industry professionals participating in the distribution, their officers and directors and each Person who controls such Persons (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) to the same extent as provided above with respect to the indemnification of the Holders of Registrable Securities, if requested. This indemnity agreement shall be in addition to any liability which the Company may otherwise have.

(b) Indemnification by Holder. In connection with each Registration Statement, each Holder shall indemnify, to the same extent as the indemnification provided by the Company in Section 6.5(a), the Company, its directors and each officer who signs the Registration Statement and each Person who controls the Company (within the meaning of Section 15 of the Securities Act

and Section 20 of the Exchange Act) but only insofar as such losses, claims, damages and liabilities arise out of or are based upon any untrue statement or omission or alleged untrue statement or omission which was made in the Registration Statement, the Prospectus or preliminary prospectus or any amendment thereof or supplement thereto, in reliance upon and in conformity with information furnished in writing by such Holder to the Company specifically for use therein. In no event shall the liability of any selling Holder of Registrable Securities hereunder be greater in amount than the dollar amount of the net proceeds received by such Holder upon the sale of the Registrable Securities giving rise to such indemnification obligation. The Company shall be entitled to receive indemnities from underwriters, selling brokers, dealer managers and similar securities industry professionals participating in the distribution, to the same extent as provided above, with respect to information so furnished in writing by such Persons specifically for inclusion in any Prospectus, Registration Statement or preliminary prospectus or any amendment thereof or supplement thereto.

(c) Conduct of Indemnification Procedure. Any party that proposes to assert the right to be indemnified hereunder will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section, notify each such indemnifying party of the commencement of such action, suit or proceeding, enclosing a copy of all papers served. No indemnification provided for in Section 6.5(a) or 6.5(b) shall be available to any party who shall fail to give notice as provided in this Section 6.5(c) if the party to whom notice was not given was unaware of the proceeding to which such notice

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would have related and was prejudiced by the failure to give such notice, but the omission so to notify such indemnifying party of any such action, suit or proceeding shall not relieve it from any liability that it may have to any indemnified party for contribution otherwise than under this Section. In case any such action, suit or proceeding shall be brought against any indemnified party and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof and the approval by the indemnified party of such counsel, the indemnifying party shall not be liable to such indemnified party for any legal or other expenses, except as provided below and except for the reasonable costs of investigation subsequently incurred by such indemnified party in connection with the defense thereof. The indemnified party shall have the right to employ its counsel in any such action, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the employment of counsel by such indemnified party has been authorized in writing by the indemnifying parties, (ii) the indemnified party shall have reasonably concluded that there may be a conflict of interest between the indemnifying parties and the indemnified party in the conduct of the defense of such action (in which case the indemnifying parties shall not have the right to direct the defense of such action on behalf of the indemnified party) or (iii) the indemnifying parties shall not have employed counsel to assume the defense of such action within a reasonable time after notice of the commencement thereof, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying parties. An indemnified party shall not be liable for any settlement of any action, suit, proceeding or claim effected without its written consent.

(d) Contribution. In connection with each Registration Statement relating to the disposition of Registrable Securities, if the indemnification provided for in subsection (a) hereof is unavailable to an indemnified party thereunder in respect to any losses, claims, damages or liabilities referred to therein, then the indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of the losses, claims, damages or liabilities referred to in paragraph (a) or (b) of this Section 6.5 in such proportion as is appropriate to reflect the relative fault

resulted in such losses, claims, damages or liabilities, or actions in respect thereof, as well as any other relevant equitable considerations. Relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the indemnifying party or the indemnified party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. Notwithstanding anything to the contrary in this Section 6.5(d), no selling Holder of Registrable Securities shall be required to contribute any amount in excess of the net proceeds it received in connection with its sale of Registrable Securities.

- (e) Underwriting Agreement to Control. Notwithstanding the foregoing provisions of this Section 6.5, to the extent that the provisions on indemnification and contribution contained in any underwriting agreement entered into in connection with the underwritten public offering of the Registrable Securities are in conflict with the foregoing provisions, the provisions in such underwriting agreement shall control.
- (f) Specific Performance. The Company and the Holder acknowledge that remedies at law for the enforcement of this Section 6.5 may be inadequate and intend that this Section 6.5 shall be specifically enforceable.
- (g) Survival of Obligations. The obligations of the Company and the Holder under this Section 6.5 shall survive the completion of any offering of Registrable Securities pursuant to a Registration Statement under this Article 6, and otherwise.

## 6.6 REPORTS UNDER SECURITIES EXCHANGE ACT OF 1934

With a view to making available to the Holders the benefits of Rule 144 promulgated under the Securities Act and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company agrees to:

(a) make and keep public information available, as those terms are understood and defined us SEC Rule 144, at all times after 90 days after the

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effective date of the first registration statement filed by the Company for the offering of its securities to the general public;

- (b) file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act; and
- (c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after 90 days after the effective date of the first registration statement filed by the Company), the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after it so qualifies), (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested in

availing any Holder of any rule or regulation of the SEC which permits the selling of any such securities without registration or pursuant to such form.

#### ARTICLE 7

#### OTHER MATTERS

#### 7.1 BINDING EFFECTS; BENEFITS

This Warrant shall inure to the benefit of and shall be binding upon the Company and the Warrantholder and their respective heirs, legal representatives, successors and assigns. Nothing in this Warrant, expressed or implied, is intended to or shall confer on any person other than the Company and the Warrantholder, or their respective heirs, legal representatives, successors or assigns, any rights, remedies, obligations or liabilities under or by reason of this Warrant.

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#### 7.2 NO INCONSISTENT AGREEMENTS

The Company will not on or after the date of this Warrant enter into any agreement with respect to its securities which is inconsistent with the rights granted to the Holders in this Warrant or otherwise conflicts with the provisions hereof. The rights granted to the Holders hereunder do not in any way conflict with and are not inconsistent with the rights granted to holders of the Company's securities under any other agreements.

## 7.3 ADJUSTMENTS AFFECTING REGISTRABLE SECURITIES

The Company will not take any action outside the ordinary course of business, or permit any change within its control to occur outside the ordinary course of business, with respect to the Registrable Securities which is without a bona fide business purpose, and which is intended to interfere with the ability of the Holders of Registrable Securities to include such Registrable Securities in a registration undertaken pursuant to this Agreement.

## 7.4 INTEGRATION/ENTIRE AGREEMENT

This Warrant is intended by the parties as a final expression of their agreement and intended to be a complete and exclusive statement of the agreement and understanding of the parties hereto in respect of the subject matter contained herein. There are no restrictions, promises, warranties or undertakings, other than those set forth or referred to herein with respect to the registration rights granted by the Company with respect to the Warrants. This Warrant supersedes all prior agreements and understandings between the parties with respect to such subject matter (other than warrants previously issued by the Company to the Warrantholder).

## 7.5 AMENDMENTS AND WAIVERS

The provisions of this Warrant, including the provisions of this sentence, may not be amended, modified or supplemented, and waivers or consents to departures from the provisions hereof may not be given unless the Company has obtained the written consent of holders of at least a majority of the outstanding Registrable Securities. Holders shall be bound by any consent authorized by this

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Section whether or not certificates representing such Registrable Securities have been marked to indicate such consent.

## 7.6 COUNTERPARTS

This Warrant may be executed in any number of counterparts and by the

parties hereto in separate counterparts, each of which so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement.

## 7.7 GOVERNING LAW

This Warrant shall be governed by and construed in accordance with the laws of the State of New York.

#### 7.8 SEVERABILITY

In the event that any one or more of the provisions contained herein, or the application thereof in any circumstances, is held invalid, illegal or unenforceable, the validity, legality and enforceability of any such provisions in every other respect and of the remaining provisions contained herein shall not be affected or impaired thereby.

#### 7.9 ATTORNEYS' FEES

In any action or proceeding brought to enforce any provisions of this Warrant, or where any provision hereof is validly asserted as a defense, the successful party shall be entitled to recover reasonable attorneys' fees and disbursements in addition to its costs and expenses and any other available remedy.

#### 7.10 COMPUTATIONS OF CONSENT

Whenever the consent or approval of Holders of a specified percentage of Registrable Securities is required hereunder, Registrable Securities held by the Company or its affiliates (other than the Warrantholder or subsequent Holders if they are deemed to be such affiliates solely by reason of their holdings of such Registrable Securities) shall not be counted in determining whether such consent or approval was given by the Holders of such required percentage.

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# 7.11 NOTICE

Any notices or certificates by the Company to the Holder and by the Holder to the Company shall be deemed delivered if in writing and delivered in person or by registered mail (return receipt requested) to the Holder addressed to him in care of [Oscar Gruss & Son Incorporated, 74 Broad Street, New York, New York 10004] [Kaufman Bros., L.P., 800 Third Avenue, New York, New York 10022], or, if the Holder has designated, by notice in writing to the Company, any other address, to such other address, and if to the Company, addressed to it at: 375 West Street, West Bridgewater, massachusetts 02379, Attention: Secretary, with a copy to Brown, Rudnick, Freed & Gesmer, P.C., One Financial Center, Boston, Massachusetts 02111, Attention: Steven R. London, Esq. or if the Company has designated, by notice in writing to the Holder, any other address, to such other address.

## 7.12 TRANSFER

Notwithstanding anything to the contrary contained herein, the Warrantholder will not sell, assign, pledge, or transfer this Warrant, except to its officers or partners, or to the officers or partners of an underwriter of the Offering for a period of one year from the date hereof.

The Company may change its address by written	notice to the Holder and
the Holder may change its address by written notice to	the Company.

IN WITNESS WHEREOF,	this Warrant has	been duly executed by the	he Company
under its corporate seal as of the	day of	, 1996.	

Ву:
Title:
Attest:
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Clerk A-35
EXERCISE FORM
(To be executed upon exercise of Warrant)
Boston Biomedica, Inc. 375 West Street West Bridgewater, Massachusetts 02379
The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant, to purchase Warrant Shares and (check one):
herewith tenders payment for of the Warrant Shares to the order of Boston Biomedica, Inc. in the amount of \$ in accordance with the terms of this Warrant; or
herewith tenders this Warrant for Warrant Shares pursuant to the net issuance exercise provisions of Section 2.3(b) of this Warrant.
Please issue a certificate or certificates for such Warrant Shares in the name of, and pay any cash for any fractional share to:
Name
(Please print Name, Address and Social Security No.) Signature
Note: The above signature should correspond exactly with the name on the first page of this Warrant Certificate or with
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assignee appearing in the assignment form below.

If said number of shares shall not be all the shares purchasable under the within Warrant Certificate, a new Warrant Certificate is to be issued in the name of said undersigned for the balance remaining of the shares purchasable thereunder.

## ASSIGNMENT

(To be executed only upon assignment of Warrant)

For value received,	hereby sells, assigns and				
transfers unto		the within Warrant, together with all right,			
	nd does hereby irrevocably constitute and appoint				
	attorney, to transfer said Warrant on the books of the				
		o the number of Warrant Shares set forth			
below, with full power of	substitution in	the premises:			
Name(s) of		No. of			
Assignee(s)	Address	Warrant Shares			
		shall not be all the Warrant Shares			
		rrant is to be issued in the name of said			
undersigned for the balan	ce remaining of	of the Warrant Shares registered by said			
Warrant.					
Dated:	Sig	nature			
Dated.	_ 518	nature			
	Note: The al	pove signature should			
		nd exactly with the			
		the face of this			
	Warrant				
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	HIBIT B				
FORM	OF LOCK-UP	AGREEMENT			
		1006			
		, 1996			

Oscar Gruss & Son Incorporated Kaufman Bros., L.P. As Representative of the several Underwriters c/o Oscar Gruss & Son Incorporated 74 Broad Street New York, New York 10004

Ladies and Gentlemen:

The undersigned understands that you propose to enter into an Underwriting Agreement (the "Underwriting Agreement") with Boston Biomedica, Inc. (the "Company") providing for the purchase by you and certain other firms (the "Underwriters") of shares (the "Shares") of Common Stock, par value \$0.01 per share (the "Common Stock"), of the Company and that the Underwriters propose to offer the Shares to the public. The undersigned further understands that the proposed sale of such Shares is the subject of a Registration Statement on Form

S-1 which will be filed with the Securities and Exchange Commission and which will include a form of preliminary prospectus to be used in offering such Shares to the public.

In consideration of the execution of the Underwriting Agreement by the Underwriters, and for other good and valuable consideration, the undersigned hereby irrevocably agrees that without the prior written consent of Oscar Gruss & Son Incorporated, which consent may be withheld in the sole discretion of Oscar Gruss & Son Incorporated, the undersigned will not (i) offer to sell, contract to sell, sell, distribute, grant any option to purchase, pledge, hypothecate, or otherwise dispose of, directly or indirectly, any shares of Common Stock, or any securities convertible into, or exercisable or exchangeable for, shares of Common Stock for a period of 180 days after the date of the final prospectus relating to the offering

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of the Shares to the public by the Underwriter except for the exercise by the undersigned of outstanding options granted by the Company or pursuant to any options granted or to be granted pursuant to employee stock option plans (but not the sale, distribution, pledge, hypothecation or other disposition of Common Stock received upon such exercise) or (ii) in connection with the offering of the Shares to the public by the Underwriter and for 365 days after the date of the final prospectus relating thereto exercise any registration rights, whether held by the undersigned on the date hereof or hereafter acquired, with respect to any shares of Common Stock, or any securities convertible into, or exercisable or exchangeable for, shares of Common Stock. Prior to the expiration of such periods, the undersigned will not announce or disclose any intention to do anything after the expiration of such periods which the undersigned is prohibited, as provided in the preceding sentence, from doing during such periods. After such periods, all shares of Common Stock owned by the undersigned may be sold or registered, as the case may be, without restriction hereunder, subject to applicable securities laws and regulations.

The undersigned agrees that the provisions of this Agreement shall be binding upon the successors, assigns, heirs and personal representatives of the undersigned.

In furtherance of the foregoing, the undersigned agrees that the Company and its transfer agent are hereby authorized to decline to make any transfer of securities if such transfer would constitute a violation or breach of this Agreement.

It is understood that, if the Underwriting Agreement does not become effective prior to \_\_\_\_\_\_, or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Shares, the undersigned's obligations under this Agreement shall terminate.

	Very truly yours,
	Ву:
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Print name and title (if applicable)

#### EXHIBIT 5.1

October 25, 1996

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

Re: Registration Statement on Form S-1 File No. 333-10759

\* 11 10 1

#### Ladies and Gentlemen:

We have acted as counsel to Boston Biomedica, Inc., a Massachusetts corporation (the "Company"), in connection with the preparation and filing with the Securities and Exchange Commission of a Registration Statement on Form S-1 (the "Registration Statement") pursuant to which the Company is registering under the Securities Act of 1933, as amended (the "Act"), 1,840,000 shares (the "Shares") of common stock, \$.01 par value (the "Common Stock"), warrants (the "Underwriters' Warrants") to purchase an aggregate of 160,000 shares of Common Stock and 160,000 shares of Common Stock (the "Warrant Shares") underlying the Underwriters' Warrants. Pursuant to the Registration Statement and an underwriting agreement (the "Underwriting Agreement") by and between the Company and Oscar Gruss & Son Incorporated and Kaufman Bros., L.P. (the "Underwriters") in substantially the form filed as Exhibit 1.1 to the Registration Statement, the Company proposes to sell to the Underwriters up to 1,840,000 shares of Common Stock (the "Shares") and will issue the Underwriters' Warrants to the Underwriters. This opinion is being rendered in connection with the filing of the Registration Statement. Unless otherwise indicated, capitalized terms used herein shall have the meanings ascribed thereto in the Underwriting Agreement.

For purposes of this opinion, we have assumed, without any investigation, (i) the legal capacity of each natural person, (ii) the full power and authority of each entity and person other than the Company to execute, deliver and perform each document heretofore executed and delivered or hereafter to be executed and delivered and to do each other act heretofore done or hereafter to be done by such entity or person, (iii) the due authorization by each entity or person other than the Company of each document heretofore executed and delivered or hereafter to be executed and delivered and to do each other act heretofore done or to be done by such entity or person, (iv) the due execution and delivery by each entity or person other than the Company of each document heretofore executed and delivered or hereafter to be executed and delivered by such entity or person, (v) the legality, validity, binding effect and enforceability as to each entity or person other than the Company of each document heretofore executed and delivered or hereafter to be executed and delivered and of each other act heretofore done or hereafter to be done by such entity or person, (vi) the genuineness of each signature on, and the completeness of each document submitted to us as an original, (vii) the conformity to the original of each document submitted to us as a copy, (viii) the authenticity of the original of each document

Boston Biomedica, Inc. Page 2 October 25, 1996

submitted to us as a copy, (ix) the completeness, accuracy and proper indexing of all governmental and judicial records searched and (x) no modification of any provision of any document, no waiver of any right or remedy and no exercise of any right or remedy other than in a commercially reasonable and conscionable manner and in good faith.

In connection with this opinion, we have examined the following (collectively, the "Documents"):

- the Amended and Restated Articles of Organization of the Company which were filed with the Secretary of State of the Commonwealth of Massachusetts on September 26, 1996;
- (ii) the Restated Bylaws of the Company, as certified by the Clerk

of the Company on September 5, 1996;

- (iii) the corporate minute books or other records of the Company pertaining to the proceedings of the stockholders and directors of the Company;
- (iv) a certificate dated October 25, 1996 of the Secretary of State of the Commonwealth of Massachusetts as to the good standing of the Company; and
- the form of Underwriting Agreement, including the form of Underwriters' Warrants attached thereto.

The opinions expressed herein are based solely upon (i) our review of the Documents, (ii) discussions with Richard T. Schumacher, Chief Executive Officer and President of the Company and Kevin W. Quinlan, the Company's Senior Vice President - Finance, Chief Financial Officer and Treasurer, (iii) the representations and warranties of the Company contained in the Underwriting Agreement, (iv) discussions with those of our attorneys who have devoted substantive attention to the matters contained herein, and (v) such review of published sources of law as we have deemed necessary.

Our opinions contained herein are limited to the laws of the Commonwealth of Massachusetts and the Federal law of the United States of America.

Based upon and subject to the foregoing, we are of the opinion that:

- 1. The Company is a corporation duly incorporated, validly existing and in good standing in the Commonwealth of Massachusetts.
- 2. The Shares to be sold by the Company under the circumstances contemplated in the Registration Statement are duly authorized and, when delivered pursuant to the Underwriting Agreement, will be validly issued, fully paid and non-assessable.

Boston Biomedica, Inc. Page 3 October 25, 1996

3. The Underwriters' Warrants, upon issuance under the circumstances contemplated in the Registration Statement and the Underwriting Agreement, will be duly authorized, executed and delivered. The Warrant Shares, upon issuance in accordance with the terms of the Underwriters' Warrants, will be duly authorized, validly issued, fully paid and non-assessable.

We understand that this opinion is to be used in connection with the Registration Statement. We consent to the filing of this opinion as an Exhibit to said Registration Statement and to the reference to our firm wherever it appears in the Registration Statement, including the prospectus constituting a part thereof and any amendments thereto. This opinion may be used in connection with the offering of the Shares only while the Registration Statement, as it may be amended from time to time, remains in effect.

Very truly yours,

By:

BROWN, RUDNICK, FREED & GESMER

By: BROWN, RUDNICK, FREED & GESMER, P.C.

/s/ Steve R. London
Steven R. London, A Member Duly
Authorized

#### EXHIBIT 10.3

STANDARD FORM 26 (REV. 4-85)

NSN 7540-01-152-8069

OMB No. 0990-0115

RFP 95-32

AWARD/CONTRACT

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

RATING

PAGE 1 OF PAGES 20

2. CONTRACT (Proc. inst. ident.) No. ND1-AI-55273

3. EFFECTIVE DATE September 30, 1995

4. REQUISITION/PURCHASE REQUEST/PROJECT N-933

5. ISSUED BY CODE 2668-55273

National Institutes of Health

Contract Management Branch, NIAID

Solar Building, Room 3007

6003 Executive Boulevard MSC 7610

Bethesda, Maryland 20892-7610

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

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, country, State and Zip

Code)

BTRL Contracts and Services, Inc., dba/

Biotech Research Laboratories, Inc.

3 Taft Court

Rockville, Maryland 20850

8. DELIVERY

FOB ORIGIN

OTHER (See below Destination)

9. DISCOUNT FOR PROMPT PAYMENT N/A

10. SUBMIT INVOICES

(4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ITEM G.3

CODE

FACILITY CODE

11. SHIP TO/MARK FOR

See Article F.1.

12. PAYMENT WILL BE MADE BY

See Article G.3.

**CODE** 

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION N/A

10 U.S.C. 2304 (c)()

41 U.S.C. 253 (c)()

14. ACCOUNTING AND APPROPRIATION DATA CAN#5-8425674 DOC#300N1A155273 TIN#1-

043152484-A1

SOC#25.55

FY 95 \$343,987

15A. ITEM NO.

15B. SUPPLIES/SERVICES

15C. QUANTITY

15D. UNIT

15E. UNIT PRICE

15F. AMOUNT

Research & Development Contract

Title: MAO/Detection of Antibodies & Proteins; Isolation of Virus (E)

Period: September 30, 1995 through September 29, 1997

Amount allotted: \$343,987 Awarded under MA N01-AI-42602

Contract Type: Cost Reimbursement/Completion

FY 95 343,987

FY 96 778,668

15G. TOTAL AMOUNT OF CONTRACT \$1,122,655

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( ) SEC. DESCRIPTION PAGE(S) ( ) SEC. DESCRIPTION PAGE(S)

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X B SUPPLIES OR SERVICES AND PRICES/COSTS 4 PART III - LIST OF DOCUMENTS,

EXHIBITS AND OTHER ATTACH.

X C DESCRIPTION/SPECS./WORK STATEMENT 8 X J LIST OF ATTACHMENTS 13

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X H SPECIAL CONTRACT REQUIREMENTS 12 M EVALUATION FACTORS FOR AWARD CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE 17. X CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 3 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

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

19A. NAME AND TITLE OF SIGNER (Type or print)

Mark Manak, Senior Vice President

20A. NAME OF CONTRACTING OFFICER

Nancy Hershey, Contracting Officer

CMB, NIAID, HIH

19B. NAME OF CONTRACTOR

BY Mark Manak

(Signature of person authorized to sign)

19C. DATE SIGNED

9/21/95

20B. UNITED STATES OF AMERICA

BY Lawrence M. Butler

(Signature of Contracting Officer)

20C. DATE SIGNED

9/22/95

# DETAILED TABLE OF MASTER AGREEMENT ORDER (MAO) CONTENTS PART I - THE SCHEDULE SECTION A - SOLICITATION/MAO FORM......1 SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS......4 ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES...... 4 ARTICLE B.2. ESTIMATED COST AND FIXED FEE...... 4 ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS......5 SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT...... 8 ARTICLE C.1. STATEMENT OF WORK...... 8 ARTICLE C.2. REPORTING REQUIREMENTS...... 8 SECTION D - PACKAGING, MARKING AND SHIPPING...... 8 ARTICLE F.2. STOP WORK ORDER...... 10 SECTION G - MAO ADMINISTRATION DATA......11 ARTICLE G.1. PROJECT OFFICER......11

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# SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

- -----

[THIS MAO IS AWARDED UNDER MASTER AGREEMENT NO1-AI-42602 FOR HIV PRECLINICAL VACCINE DEVELOPMENT].

## ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this master agreement order (MAO) is for the "Detection of Antibodies and Proteins; Isolation of Virus; Section A: Immunization with HIV Vaccines and Challenge with SHIV.

# ARTICLE B.2. ESTIMATED COST AND FIXED FEE

- a. The estimated cost of this MAO is \$1,057,412.
- b. The fixed fee for this MAO is \$65,243. The fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1 of this MAO. Payment of fixed fee shall not be made in less than monthly increments.

- c. The Government's obligation, represented by the sum of the estimated cost plus the fixed fee, is \$1,122,655.
- d. Total funds currently available for payment and allotted to this MAO are \$343,987, of which \$323,996 represents the estimated costs, and of which \$19,991 represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS referenced in Part II, ARTICLE I.2 Authorized Substitutions of Clauses of the MA.
- e. It is estimated that the amount currently allotted will cover performance of the MAO through September 29, 1996.
- f. Increments to be allotted to this contract are estimated as follows:

		Estimated	Fixed Tot	al Estim	ated
FY	Period	Cost	Fee	Cost	
				-	
95	9/30/95 - 9/2	9/96 \$ 323	3,996 \$ 1	9,991 \$	343,987
96	9/30/96 - 9/2	9/97 \$ 733	3,416 \$ 4	5,252 \$	778,668
	Total	\$1,057,412	\$ 65,243	8 \$1,122	2,655

g. The Contracting Officer may allot additional funds to the MAO without the concurrence of the MA Holder.

4

# ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

------

a. Items Unallowable Unless Otherwise Provided

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

- Acquisition, by purchase or lease, of any interest in real property;
- (2) Special rearrangement or alteration of facilities;
- (3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
- (4) Travel to attend general scientific meetings (a general scientific meeting is defined as an assemblage of scientific/technical personnel held to exchange information and ideas through a scheduled program of presentations; includes conferences, congresses, seminars, symposia and workshops; usually sponsored by a national organization);
- (5) Foreign travel See Paragraph b. below;
- (6) Overtime premium;
- (7) Consultant fees;
- (8) Subcontracts;

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

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

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#### ARTICLE B.4. ADVANCE UNDERSTANDINGS

- -----

a. The estimated level of effort set forth below is for guidance to serve not as a measure of the MAO Holder's obligation but as a further description of the required tasks. It will represent the basis of direct labor agreed to in the MAO negotiations for the period from September 30, 1995 through September 29, 1997, and will be used by both the Government and the MAO Holder to monitor progress toward achievement of the MAO objectives.

<TABLE> <CAPTION>

	Total Estimated	l Total Estim	nated Total	l Estimated
Labor Category	Year 1 I	Hours Yea	ar 2 Hours	Number of Hours
<s></s>	<c></c>	<c></c>	<c></c>	
Principal Investig	gator 400	600	1,00	0
Co-PI	520	935	1,455	
Technicians	3,472	7,415	10,887	7
TOTAL	4,392	8,950	13,342	

  |  |  |  |

- b. The MAO Holder agrees to abide by the terms of FAR 52.247-63, Preference for U.S.-Flag Air Carriers. This provision states in part that, in performing work under this MAO, the MAO Holder shall utilize U.S. flag air carriers unless service by those carriers is not available. If U.S. flag air carriers are not available the MAO Holder shall so certify in writing and include that certification/justification in the request for advance approval of foreign travel. (Cost/lower fares are not acceptable reasons for proposing to utilize foreign air carriers.)
- c. The MAO Holder agrees to submit an annual and a final inventory of Government property as required by the DHHS "Contractor's Guide for Control of Government Property." Inventories shall be submitted to the Contract Property Administrator identified in Article G.4. of this contract, with a copy to the Contracting Officer. Annual inventories

shall be submitted by October 31 each year.

- d. The MAO Holder agrees to immediately notify the Contracting Officer in writing if there is a projected overrun (in any amount) or unexpended balance (greater than 10%) in the overall budget at the end of any funding period, and the reasons for the variance (see also the requirements of the Limitation of Funds clause in the MAO).
- e. If the MAO contains any specific limitations/ceilings on particular costs, these shall always prevail until modified in the MAO.
- f. The MAO Holder agrees that samples/products received from/through the Government for utilization under this MAO shall be used only for purposes required by this MAO.
- g. Publication of Manuscripts or Abstracts

Because there is a likelihood that the MAO Holder will be evaluating proprietary compounds provided to the Government by a third party, it is essential to include provisions that will protect the rights of the third party suppliers as follows:

The MAO Holder agrees that manuscripts/abstracts based on data/information generated under this MAO will not be submitted for publication until written Project Officer clearance has been received. MAO support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information.

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The Project Officer will review all manuscripts/documents in a period of time not to exceed 30 calendar days from receipt, and will either grant clearance for publication/disclosure, recommend changes or, as applicable, refer the document to the Supplier of the compound for their review.

NIAID will use its best efforts to assist and expedite the review process by the Supplier wherever possible.

## h. Correspondence Procedures

To promote timely and effective administration, correspondence (except for invoices/financial reports, technical progress reports/other deliverables) submitted under this MAO shall be subject to the following procedures:

- Technical correspondence shall be addressed to the Project Officer with an information copy of the basic correspondence to the Contracting Officer. (As used herein, technical correspondence excludes correspondence which proposes deviations from or modifications of MAO requirements, terms or conditions.)
- 2. Other correspondence shall be addressed to the Contracting Officer, with an information copy of the basic correspondence to the Project Officer.
- Subject Line(s). All correspondence shall contain a subject line commencing with the MAO number as illustrated below:

SUBJECT: MAO No. NO1-AI-55273 Request for Approval of

#### SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

\_\_\_\_\_

# ARTICLE C.1. STATEMENT OF WORK

- -----

- a. Independently and not as an agent of the Government, the MAO Holder shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, SECTION J, ATTACHMENT 1, dated September 30, 1995 attached hereto and incorporated herein.
- b. If there is any inconsistency between the MAO Holder's technical proposals dated March 7, 1995, June 20, 1995 and August 7, 1995, and the work described in this Article C.1., Paragraph a., the terms and conditions of this Article C.1., Paragraph a, shall control.

#### ARTICLE C.2. REPORTING REQUIREMENTS

- -----

#### a. Technical Reports

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

## (1) Quarterly Progress Report

By the fifteenth calendar day of the month following the end of each quarter, the MA Holder shall submit (5) copies of a quarterly technical report. Four (4) copies shall be submitted to the Project Officer and one (1) copy shall be submitted to the Contracting Officer. This report shall include a (description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months. A quarterly report shall not be submitted when a final report is due.

# (2) Final Report

The MAO Holder shall submit five (5) copies of the final report documents. Four (4) copies shall be submitted to the Project Officer and (1) copy shall be submitted to the Contracting Officer. This report is to include a summation of the work performed and results obtained for the entire MAO period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted no later than the completion date of this MAO.

#### SECTION D - PACKAGING, MARKING AND SHIPPING

- -----

All deliverables required under this MAO shall be packaged, marked and shipped in accordance with Government specifications. The MAO Holder shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

#### SECTION E - INSPECTION AND ACCEPTANCE

- -----

- a. For the purpose of this ARTICLE, the designated Project Officer is the authorized representative of the Contracting Officer, who shall perform inspection and acceptance of materials and services to be provided.
- b. Inspection and acceptance will be performed at the Project Officer's address listed in the clause entitled "Deliveries" in Section F.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

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

FAR Clause 52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT - (SHORT FORM)(APRIL 1984).

9

#### SECTION F - DELIVERIES OR PERFORMANCE

- -----

## ARTICLE F.1. DELIVERIES

- -----

Satisfactory performance of this MAO shall be deemed to occur upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

The items specified below as described in (SECTION C, ARTICLE C.2. shall be delivered f.o.b. destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this MAO]:

Item	Description	QuantityDelivery Schedule
1.	Quarterly	5 1/15/96, 97 4/15/96, 97
		7/15/96, 97
		10/15/96
2.	Final	5 By completion date of this MAO

The above items shall be addressed and delivered to:

Addressee	Deliverable Item	ı No.	Quantity
Project Officer	1.	4	
PRB, DAIDS	2.	4	

Solar Bldg., Rm. 2A31 6003 Executive Blvd.

Bethesda, MD. 20892

Contracting Officer 1. 1
CMB, DEA, NIAID, NIH 2. 1
Solar Bldg., Rm. 3C07
6003 Executive Blvd.
Bethesda, MD. 20892

#### ARTICLE F.2. STOP WORK ORDER

- -----

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE: 52.212-13, STOP WORK ORDER (AUGUST 1989) with ALTERNATE I (APRIL 1984).

10

#### SECTION G - MAO ADMINISTRATION DATA

- -----

#### ARTICLE G.1. PROJECT OFFICER

\_ \_\_\_\_\_

Pursuant to the Project Officer Article incorporated in the MA, the following Project Officer will represent the Government for the purpose of this MAO:

MAO Project Officer: Marta J. Glass, M.S.

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

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

The Government may unilaterally change its Project Officer designation.

#### ARTICLE G.2. KEY PERSONNEL

- -----

Pursuant to the Key Personnel clause incorporated in the MAO, the following individuals are considered to be essential for the work being performed hereunder:

NAME TITLE

Chang Chih-Tai, Ph.D. Principal Investigator Hanna Weissberger, Ph.D. Co-Principal Investigator

# ARTICLE G.3. INVOICE SUBMISSION

- -----

The Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, set forth in your Master Agreement are incoporated herein.

The invoice instructions and directions for the submission of invoice/financing requests contained in the MA must be followed to meet the requirements of a "proper" invoice, pursuant to FAR 32.9.

11

#### ARTICLE G.4. GOVERNMENT PROPERTY

- -----

a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in this Section I of this MAO, the MAO Holder shall comply with the provisions of DHHS Publication, Contractor's Guide for Control of Government Property, (1990), which is incorporated into this MAO by reference. Among other issues, this publication provides a summary of the MAO Holder's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the MAO. A copy of this publication is available upon request to the Contract Property Administrator at the following address:

Contracts Property Administrator Research Contracts Property Administration, NIH Building 13, Room 2E-65 9000 Rockville Pike Bethesda, Maryland 20892 (301) 496-6466

ARTICLE G.5. GOVERNMENT SUPPLY SOURCES, is hereby incorporated into this MAO by reference pursuant to the Master Agreement.

# SECTION H - SPECIAL MASTER AGREEMENT ORDER REQUIREMENTS

- -----

The following Articles are incorporated into this MAO by reference pursuant to the Master Agreement. [(Any MAO Articles which are not contained in the MA are set forth below in full text)]:

- a. ARTICLE H.1. HUMAN SUBJECTS
- b. ARTICLE H.2. SALARY RATE LIMITATION LEGISLATION PROVISIONS

Paragraph b. of this ARTICLE is revised as follows:

# PART II

- -----

#### SECTION I - MASTER AGREEMENT ORDER CLAUSES

- -----

The following Articles are incorporated into this MAO by reference pursuant to the Master Agreement. [(Any MAO Articles which are not contained in the MA are set forth below in full text)]:

- a. ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST PLUS A FIXED FEE MASTER AGREEMENT ORDER
- b. ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES, [Cost-Reimbursement]
- c. ARTICLE I.3. ADDITIONAL MASTER AGREEMENT CLAUSES, [Cost-Reimbursement]
- d. ARTICLE I.4. ADDITIONAL FAR CLAUSES INCLUDED IN FULL TEXT

PART III

- -----

#### SECTION J - LIST OF ATTACHMENTS

- -----

Unless otherwise indicated below, the following documents are attached and incorporated in this MAO:

- 1. Statement of Work, September 30, 1995, 7 pages.
- Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1 6/18/92, 4 pages. [This attachment is part of the Master Agreement document and is incorporated into this MAO by reference].
- 3. Safety and Health, PHSAR clause 352.223-70, (4/84), 2 pages. [This attachment is part of the Master Agreement document and is incorporated into this MAO by reference.
- 4. Procurement of Certain Equipment, NIH(RC)-7, (4/1/84), 1 page. [This attachment is part of the Master Agreement document and is incorporated into this MAO by reference.

#### SECTION K - REPRESENTATIONS AND CERTIFICATIONS

- -----

The following documents are incorporated by reference in this MAO:

1. Representations and Certifications, dated August 7, 1995.

END of the SCHEDULE (MASTER AGREEMENT ORDER)

13

STATEMENT OF WORK

-----

SECTION A: IMMUNIZATION WITH HIV VACCINES AND CHALLENGE WITH SHIV

Independently, and not as an agent of the Government, the Master Agreement Order holder shall provide the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the tasks of the Statement of Work below:

The MAO Holder shall:

- 1. Perform assays to assess the humoral immune responses of macaques that have been immunized with HIVenv (or with a combination of HIVenv and SIV non-env) vaccines. Specifically the MAO Holder shall:
  - a. Conduct assays (such as ELISA and western blots) to detect antibodies to the envelope of HIV (and to non-envelope proteins of SIV that are included in the immunization protocol) in the sera or other fluids of immunized or virus-infected monkeys for all vaccine studies assigned.
  - b. Develop assays to detect antibodies to the above proteins or antigens if an assay system is not currently available to detect those antibodies or if existing assays are not of sufficient sensitivity or specificity to provide the information required by NIAID.

MAO Statement of Work (09/30/95)

ATTACHMENT 1 Page 1

- Conduct assays to determine whether monkeys become infected after exposure to SHIV:
  - a. Determine whether SHIV can be isolated from PBMC, lymph nodes, or other tissue of monkeys after virus challenge by co-cultivating the cells or tissue with primary simian and/or human peripheral blood cells, other primary cells, and/or cell lines. Evaluate the virus load in the PBMC of infected monkeys by conducting limitingdilution virus isolations.
    - Confirm virus transmission to the target cells by demonstration of the presence of virus or viral protein(s) in the culture supernatant and/or the presence of viral protein or nucleic acid in the cultured cells.
  - b. Conduct assays to detect HIV proteins and/or SIV proteins, or SHIV nucleic acids (using HIV or SIV primers or probes, as appropriate) in peripheral blood lymphocytes or other tissues of animals after challenge with virus.
  - c. Conduct assays (such as antigen capture assays) to detect viral antigens or conduct assays to detect viral nucleic acids in the plasma of animals after challenge with virus.

MAO Statement of Work (09/30/95)

ATTACHMENT 1 Page 2

- 3. Receive, catalog, track, and maintain an inventory of the specimens that arrive for evaluation:
  - a) Advise sample suppliers (Category B MAO contractors) of the most suitable manner for shipment of sera, whole blood, cells or other specimens for evaluation and arrange for the transfer of these specimens from primate laboratories to the MAO Holder. All shipments must be coordinated so that activity/viability of specimens will not be adversely affected.
  - b) When necessary, pick up or arrange for pick up of incoming specimen shipments from a specified airport or other contact site in a timely manner and assure maintenance of activity and/or viability of the specimens by providing the appropriate temperature in transit from the airport or other contact site to the MAO Holder's laboratory.
  - c) Receive and catalog specimens arriving for evaluation from the primate laboratories. Maintain documentation on file for all incoming specimens, including but not limited to:primate subject identification number, trial site, protocol identification number, specimen collection date and condition of sample upon arrival.
  - d) Store cataloged, aliquotted specimens under appropriate conditions to retain maximum immunological activity.
  - e) Maintain specimen tracking and inventory system such that specimens can be traced and located from receipt through processing and assay analysis.
- 4. Maintain test result database and transfer data electronically:
  - a) Compile and maintain a computerized database of all assay and virus isolation results, using a format compatible with the FOX-PRO data base that NIAID plans to use to compile records and data from the vaccine studies. Results are to be recorded with designations of study protocol number, animal number, specimen collection date, and other information requested by the Project Officer.
  - b) Transfer specified data electronically to the AIDS Vaccine Evaluation Group (AVEG) Statistical and Coordinating Center (SCC) and to the Project Officer at regular intervals as instructed by the Project Officer (Format to be agreed upon betwen NIAID and the MAO Holder).

MAO Statement of Work (09/30/95)

ATTACHMENT 1 Page 3

- c) Ensure protection against the loss of data by the duplication of data base files and programs for storage; provide for the security and safety of data on the specimen inventory and the test results database.
- 5. Provide facilities and resources:
  - a) Provide facilities and equipment for the work to be conducted, including a biosafety level 2 or 3 laboratory for conducting work with live HIV and SHIV as well as samples from infected monkeys.
  - b) Provide, maintain, and operate facilities for controlled storage of sera, virus stocks, cell stocks, and other samples and reagents, including storage at -10 to -20 degrees C, at -70 to 90 degrees C, and in liquid nitrogen conditions, with appropriate monitoring of storage conditions to guarantee continuous proper storage. The reliability of supply systems, electrical power, and backup support systems shall be ensured by the MAO Holder.

- c) Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous materials, including radioactive materials. Specifically, the MAO Holder shall comply with all applicable health and safety regulations while conducting the work set forth herein.
- d) Conduct work under this MAO in accordance with all applicable Federal, state, and local laws, codes, ordinances and regulations, and with the following basic references and other related modifications by the Public Health Service:
  - (1) Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for Disease Control and National Institutes of Health, HHS Pub. No. (NIH) 93-8395 published by the U.S. Government Printing Office, third edition, May 1993, stock number 17-040-00523-7.
  - (2) Recommendations for Prevention of HIV Transmission in Health Care Settings, Morbidity and Mortality Weekly Report, Vol. 36, No. 2-S.
  - (3) Agent Summary Statement for Human Immunodeficiency Virus and Report on Laboratory-Acquired Infection with Human Immunodeficiency Virus, Morbidity and Mortality Weekly Report, Vol. 37, No.S-4, pp.1-22.
  - (4) "Guidelines to Prevent Simian Immunodeficiency Virus Infection in Laboratory Workers and Animal Handlers," Morbidity and Mortality Weekly Report, Vol. 37, No. 45, pp. 693-704.

MAO Statement of Work (09/30/95)

ATTACHMENT 1 Page 4

- 6. Designate a project coordinator to manage the day-to-day conduct of the study, to interact with the Category B MAO laboratory or laboratories providing non-human primate samples from the vaccine study or studies, and to provide information on the status of the assay results to the Project Officer.
- 7. Report data and results to NIAID or to a designated NIAID contractor. Printouts of data and verbal reports of the status of the study are to be provided on an ongoing basis during the course of the study at the request of the Project Officer, in addition to the required periodic (quarterly and final) written reports describing the progress of the study, and in addition to the periodic electronic transfer of data described in item (6) above.

MAO Statement of Work (09/30/95)

ATTACHMENT 1 Page 5

SUMMARY OF VACCINE STUDIES FOR WHICH ASSAYS WILL BE REQUIRED

(SECTION A: IMMUNIZATION WITH HIV VACCINES AND CHALLENGE WITH SHIV)

VACCINE STUDY 4

- -----

Title: Testing of Recombinant Poxvirus/HIV Together with Recombinant Poxvirus/SIV Vaccines in the SHIV Model

Description: Rhesus monkeys will be immunized with recombinant vaccina expressing HIV-1 env, recombinant vaccina expressing SIV non-envelope genes or with both; monkeys will be immunized with recombinant fowlpox expressing HIV-1 env, recombinant fowlpox expressing SIV non-envelope genes, or with both. Immunized monkeys will be boosted with purified HIV-1 env protein and/or with SIV proteins. Monkeys will be challenged with a SHIV. The experiment is designed to evaluate the contribution of env versus non-env immune responses in providing protection from infection and to compare the efficacy of vaccinia-based versus fowlpox-based vaccines when followed by a protein boost.

Number of monkeys: 48 (8 groups of 6)

Length of study: 18 months

Number of inoculations per animal: 5 immunizations plus 1 virus challenge

Number of bleeds per animal: approximately 40

#### **VACCINE STUDY 13**

- -----

Title: Immunogenicity of a Soluble Oligomeric Form of the HIV-1 Envelope Protein

Description: Rhesus monkeys will be immunized with a purified oligomeric form of the HIV-1 envelope protein to determine if monkeys will generate antibodies (presumably to conformational epitopes of the oligomeric envelope) that are able to neutralize genetically divergent strains of HIV-1. Vaccines based on monomeric forms of the HIV-1 envelope generate predominantly type-specific antibodies that neutralize a limited range of HIV-1 isolates, but preliminary studies with the oligomeric form of the envelope indicate that antibodies to it may be more broadly reactive. Animals will be challenged with SHIV after immunization to determine the ability of the immune response to the oligomeric envelope to protect monkeys from infection.

MAO Statement of Work (09/30/95)

ATTACHMENT 1 Page 6

Number of monkeys: 36 (6 groups of 6)

Length of study: 24 months

Number of inoculations per animal: 5 immunizations plus 1 virus challenge

# VACCINE STUDY 16

- -----

Title: Evaluation of a Recombinant Semliki Forest Virus/HIV Vaccine

Description: Rhesus monkeys will be immunized with an avirulent recombinant Semliki Forest virus expressing HIV-1 envelope and SIV gag proteins. The monkeys will be infected with the virus, which has a broad tissue tropism, by either intramuscular, intravenous, subcutaneous, or mucosal site administration. Animals will be challenged with SHIV to determine the efficacy of this vaccine in protecting from virus infection.

Number of monkeys: 10 (5 groups of 2)

Length of study: 18 months

Number of inoculations per animal: 8 immunizations plus 1 virus challenge

MAO Statement of Work

ATTACHMENT 1
(09/30/95)

Page 7

#### EXHIBIT 10.4

STANDARD FORM 26 (REV. 4-85)

NSN 7540-01-152-8069

OMB No. 0990-0115

RFP 95-3

AWARD/CONTRACT

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

RATING

PAGE 1 OF PAGES 21

2. CONTRACT (Proc. inst. ident.) No. NO1-AI-55277

3. EFFECTIVE DATE September 30, 1995

4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 000948

5. ISSUED BY CODE 2668-55277

National Institutes of Health

Contract Management Branch, NIAID

Solar Building, Room 3007

6003 Executive Boulevard MSC 7610

Bethesda, Maryland 20892-7610

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

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, country, State and Zip

Code)

BTRL Contracts and Services, Inc., dba/

Biotech Research Laboratories

3 Taft Court

Rockville, Maryland 20850

8. DELIVERY

FOB ORIGIN

OTHER (See below) DESTINATION

9. DISCOUNT FOR PROMPT PAYMENT N/A

10. SUBMIT INVOICES

(4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN

ITEM G.3

**CODE** 

FACILITY CODE

11. SHIP TO/MARK FOR

See Article F.1.

12. PAYMENT WILL BE MADE BY

See Article G.3.

CODE

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION N/A

10 U.S.C. 2304 (c)( )41 U.S.C. 253(c)( )

14. ACCOUNTING AND APPROPRIATION DATA

CAN#58425674 (Amount Obligated - \$387,353)

DOC#300N1A155277

EIN#1-043152484-A1

SOC#25.55

15A. ITEM NO.

15B. SUPPLIES/SERVICES

15C. QUANTITY

15D. UNIT

15E. UNIT PRICE

15F. AMOUNT

Research & Development Contract

Title: MAO/Assessment of Humoral Immune Responses (G)

Period: September 30, 1995 through September 29, 1997

Amount allotted: \$387,353 Awarded under MA N01-AI-42602

Contract Type: Cost Reimbursement/Completion

FY 95 387,353

FY 96 226,739

15G. TOTAL AMOUNT OF CONTRACT \$614,092

16. TABLE OF CONTENTS

( ) SEC. DESCRIPTION PAGE(S) ( ) SEC. DESCRIPTION PAGE(S)

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X B SUPPLIES OR SERVICES AND PRICES/COSTS 3 PART III - LIST OF DOCUMENTS,

EXHIBITS AND OTHER ATTACH.

X C DESCRIPTION/SPECS./WORK STATEMENT 7 X J LIST OF ATTACHMENTS 12  $\,$ 

X D PACKAGING AND MARKING 7 PART IV- REPRESENTATIONS AND INSTRUCTIONS

X E INSPECTION AND ACCEPTANCE 7 X K REPRESENTATIONS, CERTIFICATIONS AND OTHER

STATEMENTS OF OFFERORS 13

X G CONTRACT ADMINISTRATION DATA 9

11 L INSTRS., CONDS., AND NOTICES TO OFFERORS
X H SPECIAL CONTRACT REQUIREMENTS 10 M EVALUATION FACTORS FOR AWARD
CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE
17. X CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 3 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Numbers including the fall additions are hearest made herever which

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

19A. NAME AND TITLE OF SIGNER (Type or print)

Mark Manak, Senior Vice President

20A. NAME OF CONTRACTING OFFICER

Jacqueline C. Holden, Contracting Officer

AIDS Preclinical Research Contract Section, CMB, NIAID, HIH

19B. NAME OF CONTRACTOR

BY Mark Manak

(Signature of person authorized to sign)

19C. DATE SIGNED

9/25/95

20B. UNITED STATES OF AMERICA

BY Jacqueline C. Holden

(Signature of Contracting Officer)

20C. DATE SIGNED

9/27/95

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		-	N OE CLIDD	LIEC OD CEDVICEC		
		TEF DESCRIPTION		LIES OR SERVICES		
Tŀ	ne purpose of this	s master agreement	t order (Ma	AO) is for the Assessment o	f	
Ηι	umoral Immune R	Response.				
Al	RTICLE B.2. ES	TIMATED COST A	AND FIXEI	FEE		
 a.	The estimated of	cost of this MAO is	\$573.918			
b.			•	fixed fee shall be paid in		
υ.	installments bas	sed on the percentag	ge of compl	etion of work, as determined		
				holding provisions of the T AND FIXED FEE reference	ced in the General	
		n PART II, ARTIC		is MAO. han monthly installments.		
	•			•		
c.	The Government's obligation, represented by the sum of the estimated cost plus fixed fee, is \$614,092.					
d.	\$387,353 of wh \$25,341 represe the LIMITATIO	ich \$362,012 represents the fixed fee. FON OF FUNDS co	sents the est For further plause refere	and allotted to this MAO are imated costs, and of which provisions on funding see need in Part II, ARTICLE ter Agreement (MA).	1.2.	
e.	It is estimated t		ently allotte	ed will cover performance		
f.		e allotted to this cor		imated as follows:		
<7	TABLE> CAPTION>					
~(	FY Period	Estimated d Cost	Fixed Fee	Total Estimated Cost Plus Fee		
		< <c></c>	 <c></c>			
	···	\C_	~C/	`~~		

95 09/30/95 - 09/29/96 \$362,012 \$25,341 \$387,353 96 09/30/96 - 09/29/97 \$211,906 \$14,833 \$226,739

Totals \$573,918 \$40,174 \$614,092

</TABLE>

g. The Contracting Officer may allot additional funds to the MAO without the concurrence of the MAO Holder.

#### ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

- -----

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clause(s), ALLOWABLE COST AND PAYMENT, [and FIXED FEE,] incorporated in this MAO, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

- (1) Acquisition, by purchase or lease, of any interest in real property;
- (2) Special rearrangement or alteration of facilities;
- (3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

3

- (4) Travel to attend general scientific meetings (a general scientific meeting is defined as an assemblage of scientific/technical personnel held to exchange information and ideas through a scheduled program of presentations; includes conferences, congresses, seminars, symposia and workshops; usually sponsored by a national organization);
- (5) Foreign travel See Paragraph b. below;
- (6) Overtime premium;
- (7) Consultant fees;
- (8) Subcontracts;
- (9) Accountable Government property (defined as both real and personal property with an acquisition cost of \$1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide for Control of Government Property, 1990, regardless of acquisition value.
- b. Travel Costs
- (1) Domestic Travel
  - (a) Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this MAO shall not exceed \$-0- without the prior written approval of the Contracting Officer.

(Domestic travel is defined as MA Holder travel directly applicable to performance under this MAO; includes travel to discuss progress under this MAO with the Project Officer or Contracting Officer or to attend meetings, called by the NIAID, of collaborating program investigators to discuss program progress and plans. The domestic travel amount above does not include scientific meeting travel which

is defined in Article B.3.a. above and which shall be specifically approved in writing by the Contracting Officer.)

- (b) The cost of travel by privately-owned automobile shall be reimbursed at the mileage rate prescribed by the MA Holder's established, generally applicable travel policy in lieu of actual costs, provided, however, that such reimbursement shall not exceed the otherwise allowable comparative cost of travel by common carrier.
- (c) Reasonable actual costs of lodging and subsistence, or per diem in lieu of actual costs, shall be allowable to the extent that such actual costs or per diem amounts do not exceed the amounts or per diem rates prescribed by the MA Holder's established, generally applicable travel policy.
- (d) Any revision to the MA Holder's established, generally applicable travel policy submitted to the cognizant audit agency during the period of performance of this MAO shall be effective, without formal modification to this MAO, upon delivery to the Contracting Officer of notice describing such revised policy together with evidence of submission thereof to the cognizant audit agency.

#### (2) Foreign Travel

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

4

# ARTICLE B.4. ADVANCE UNDERSTANDINGS

- -----

a. The estimated level of effort set forth below is for guidance to serve not as a measure of the MAO Holder's obligation but as a further description of the required tasks. It will represent the basis of direct labor agreed to in the MAO negotiations for the period from September 30, 1995 through September 29, 1997, and will be used by both the Government and the MAO Holder to monitor progress toward achievement of the MAO objectives.

Total	Estimated	Total Estimated	d Total	Estimated
Labor Category	Year 1 H	lours Year 2 I	Hours	Number of Hours
Principal Investigator	375	375	750	)
Co-Investigator	1,404	749	2,153	3
Technician	1,872	1,872	3,744	
Technician	1,872	936	2,808	
Technician	1,872	0	1,872	
TOTAL	7.395	3.932	11.327	7

b. The total costs negotiated for this MAO only cover Vaccine Studies in support of Section B of the Statement of Work. Section A of the Statement of Work is also attached to this contract should it be necessary to perform assays in support of Vaccine Studies for Section A. If it is necessary to perform Section A assays, the costs for those assays shall be

offset against the cost negotiated for performance of Section B assays.

- c. The MAO Holder agrees to abide by the terms of FAR 52.247-63, Preference for U.S.-Flag Air Carriers. This provision states in part that, in performing work under this MAO, the MAO Holder shall utilize U.S. flag air carriers unless service by those carriers is not available. If U.S. flag air carriers are not available the MAO Holder shall so certify in writing and include that certification/justification in the request for advance approval of foreign travel. (Cost/lower fares are not acceptable reasons for proposing to utilize foreign air carriers.)
- d. The MAO Holder agrees to submit an annual and a final inventory of Government property as required by the DHHS "Contractor's Guide for Control of Government Property." Inventories shall be submitted to the Contract Property Administrator identified in Article G.4. of this contract, with a copy to the Contracting Officer. Annual inventories shall be submitted by October 31 each year.
- e. The MAO Holder agrees to immediately notify the Contracting Officer in writing if there is a projected overrun (in any amount) or unexpended balance (greater than 10%) in the overall budget at the end of any funding period, and the reasons for the variance (see also the requirements of the Limitation of Funds clause in the MAO).
- If the MAO contains any specific limitations/ceilings on particular costs, these shall always prevail until modified in the MAO.
- g. The MAO Holder agrees that samples/products received from/through the Government for utilization under this contract shall be used only for purposes required by this MAO.
- h. Publication of Manuscripts or Abstracts

Because there is a possibility that the MAO Holder will be evaluating proprietary compounds provided to the Government by a third party, it is essential to include provisions that will protect the rights of the third party suppliers as follows:

The MAO Holder agrees that manuscripts/abstracts based on data/information generated under this MAO will not be submitted for publication until written Project Officer clearance has been received. MAO support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information.

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The Project Officer will review all manuscripts/documents in a period of time not to exceed 30 calendar days from receipt, and will either grant clearance for publication/disclosure, recommend changes or, as applicable, refer the document to the Supplier of the compound for their review. NIAID will use its best efforts to assist and expedite the review process by the Supplier wherever possible.

### i. Correspondence Procedures

To promote timely and effective administration, correspondence (except for invoices/financial reports, technical progress reports/other deliverables) submitted under this MAO shall be subject to the following procedures:

- Technical correspondence shall be addressed to the Project Officer
  with an information copy of the basic correspondence to the
  Contracting Officer. (As used herein, technical correspondence
  excludes correspondence which proposes deviations from or
  modifications of MAO requirements, terms or conditions.)
- Other correspondence shall be addressed to the Contracting Officer, with an information copy of the basic correspondence to the Project Officer.

3. Subject Line(s). All correspondence shall contain a subject line commencing with the contract number as illustrated below:

SUBJECT: Contract No. NO1-AI-55277 Request for Approval of

6

#### SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

- -----

#### ARTICLE C.1. STATEMENT OF WORK

\_ \_\_\_\_\_

- a. Independently and not as an agent of the Government, the MAO Holder shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, SECTION J, ATTACHMENT 1, dated September 30, 1995, attached hereto and incorporated herein.
- b. If there is any inconsistency between the MAO Holder's technical proposal and the work described in this Article C.1., Paragraph a., the terms and conditions of this Article C.1., Paragraph a, shall control.

#### ARTICLE C.2. REPORTING REQUIREMENTS

- -----

#### a. Technical Reports

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

# (1) Quarterly Progress Report

By the fifteenth calendar day of the month following the end of each quarter, the MAO Holder shall submit (5) copies of a quarterly technical report. Four (4) copies shall be submitted to the Project Officer and one (1) copy shall be submitted to the Contracting Officer. This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months. A quarterly report shall not be submitted when a final report is due.

#### (2) Final Report

The MAO Holder shall submit five (5) copies of the final report documents. Four (4) copies shall be submitted to the Project Officer and (1) copy shall be submitted to the Contracting Officer. This report is to include a summation of the work performed and results obtained for the entire MAO period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted no later than the completion date of this MAO.

#### SECTION D - PACKAGING, MARKING AND SHIPPING

- -----

All deliverables required under this MAO shall be packaged, marked and shipped in accordance with Government specifications. The MAO Holder shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

#### SECTION E - INSPECTION AND ACCEPTANCE

- -----

- a. For the purpose of this ARTICLE, the designated Project Officer is the authorized representative of the Contracting Officer, who shall perform inspection and acceptance of materials and services to be provided.
- b. Inspection and acceptance will be performed at the Project Officer's address listed in the clause entitled "Deliveries" in Section F.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

c. This MAO incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.
 FAR Clause 52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT - (SHORT FORM)(APRIL 1984).

7

#### SECTION F - DELIVERIES OR PERFORMANCE

- -----

#### ARTICLE F.1. DELIVERIES

- -----

a. Satisfactory performance of this MAO shall be deemed to occur upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

The items specified below as described in (SECTION C, ARTICLE C.2. shall be delivered f.o.b. destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this MAO]:

Item	Descriptio	n (	Quantity Delivery Schedule
1.	Quarterly		5 01/15/96, 97, 04/15/96, 97, 07/15/96, 97, 10/15/96
2.	Final	5	By completion date of this contract

The above items shall be addressed and delivered to:

Addressee	Deliverable Item No.	Quantity
Project Officer PRB, DAIDS Solar Bldg., Rm. 2A38	a.1. a.2.	4 4
6003 Executive Blvd. Bethesda, MD. 20892		
Contracting Officer CMB, DEA, NIAID, N Solar Bldg., Rm. 3C07 6003 Executive Blvd. Bethesda, MD. 20892	a.1. IH a.2.	1 1

#### ARTICLE F.2. STOP WORK ORDER

- -----

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE: 52.212-13, STOP WORK ORDER (AUGUST 1989) with ALTERNATE I (APRIL 1984).

8

#### SECTION G - CONTRACT ADMINISTRATION DATA

- -----

#### ARTICLE G.1. PROJECT OFFICER

- -----

Pursuant to the Project Officer Article incorporated in the MA, the following Project Officers will represent the Government for the purpose of this MAO:

MAO Project Officer: Nancy Miller, Ph.D.

#### ARTICLE G.2. KEY PERSONNEL

- -----

Pursuant to the Key Personnel clause incorporated in the MA, the following individuals are considered to be essential to the work being performed hereunder:

NAME TITLE

Mark Cosentino, Ph.D. Principal Investigator Hanna Weissberger, Ph.D. Co-Investigator

#### ARTICLE G.3. INVOICE SUBMISSION

- -----

#### a. INVOICE SUBMISSION - COST-REIMBURSEMENT MAOS

The Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, set forth in your Master Agreement are incorporated berein

The invoice instructions and directions for the submission of invoice/financing requests contained in the MA must be followed to meet the requirements of a "proper" invoice, pursuant to FAR 32.9.

### ARTICLE G.4. GOVERNMENT PROPERTY

- -----

a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in this Section I of this MAO, the MAO Holder shall comply with the provisions of DHHS Publication, Contractor's Guide for Control of Government Property, (1990), which is incorporated into this MAO by reference. Among other issues, this publication provides a summary of the MAO Holder's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the MAO. A copy of this publication is available upon request to the Contract Property Administrator at the following address:

Contracts Property Administrator Research Contracts Property Administration, NIH Building 13, Room 2E-65 9000 Rockville Pike Bethesda, Maryland 20892 (301) 496-6466

ARTICLE G.5. GOVERNMENT SUPPLY SOURCES, is hereby incorporated into this MAO by reference pursuant to the Master Agreement.

9

# SECTION H - SPECIAL MASTER AGREEMENT ORDER REQUIREMENTS

\_\_\_\_\_\_

The following Articles are incorporated into this MAO by reference pursuant to the Master Agreement. [(Any MAO Articles which are not contained in the MA are set forth below in full text)]:

a. ARTICLE H.1. HUMAN SUBJECTS

-----

b. ARTICLE H.2. SALARY RATE LIMITATION LEGISLATION PROVISIONS

Paragraph b. of this ARTICLE is revised as follows:

b. Public Law No.		Fiscal Year		Salary Lin	nitation
	103-333	1995	\$	8125,000	

10

PART II

# SECTION I - MASTER AGREEMENT ORDER CLAUSES

- -----

The following Articles are incorporated into this MAO by reference pursuant to the Master Agreement. [(Any MAO Articles which are not contained in the MA are set forth below in full text)]:

- a. ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT MASTER AGREEMENT ORDER
- b. ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES]

For this Master Agreement Order (N01-AI-55277), FAR Clause 52.232-22, LIMITATION OF FUNDS, (APRIL 1984) as contained in MA N01-AI-42602 is deleted in its entirety and is replaced with FAR Clause 52.232-20, LIMITATION OF COSTS.

- c. ARTICLE I.3. ADDITIONAL MASTER AGREEMENT CLAUSES
- d. ARTICLE I.4. ADDITIONAL FAR CLAUSES INCLUDED IN FULL TEXT

PARTIII
SECTION J - LIST OF ATTACHMENTS

Unless otherwise indicated below, the following documents are attached and incorporated in this MAO:

- 1. Statement of Work, September 30, 1995; 8 pages.
- 2. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1 (6/18/92), 4 pages. [This attachment is part of the Master Agreement document and is incorporated into this MAO by reference.]
- 3. Safety and Health, PHSAR Clause 352.223-70, (4/84), 2 pages. [This attachment is part of the Master Agreement document and is incorporated into this MAO by reference.]
- 4. Procurement of Certain Equipment, NIH(RC)-7, (4/1/84), 1 page. [This attachment is part of the Master Agreement document and is incorporated into this MAO by reference.]

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PART IV

# SECTION K - REPRESENTATIONS AND CERTIFICATIONS

- -----

The following documents are incorporated by reference in this MAO:

1. Representations and Certifications, dated September 15, 1995.

END of the SCHEDULE (MASTER AGREEMENT ORDER)

13

MASTER AGREEMENT ORDER FOR CATEGORY G  ${\bf STATEMENT\ OF\ WORK}$ 

Independently, and not as an agent of the Government, the Master Agreement Order holder shall provide the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the tasks of the Statement of Work below:

The MAO Contractor shall perform assays to assess and characterize the humoral immune responses of macaques that have been immunized with HIVenv or with a combination of HIVenv and SIV non-env vaccines. Specifically the MAO Contractor shall:

- 1. Conduct assays to determine the ability of sera or mucosal secretions from monkeys immunized with HIV vaccines (or of sera from infected monkeys after SHIV challenge) to neutralize infection of cell lines and/or primary cells (PBMC) by the HIV strain used for the vaccine. Further characterize the antibodies, including determining the neutralization titer against the vaccine (homologous) HIV strain. If the appropriate SHIV virus stock is available, determine the ability of the sera to neutralize the SHIV made with the envelope gene of the homologous (vaccine) HIV.
- 2. For sera (or mucosal secretions) that were determined (above) to neutralize the homologous strain of HIV, determine the neutralization titer against infection of T cell lines and/or PBMC by heterologous laboratory strains of HIV.
- 3. For sera (or mucosal secretions) that show the ability to neutralize heterologous HIV isolates (above), determine the ability to neutralize infection of T cell lines and/or primary PBMC and/or primary macrophages by primary, "field" isolates of HIV grown only in primary cells.
- 4. Prior to conducting neutralization assays with the monkey sera from the vaccine studies, grow appropriate HIV and SHIV virus stocks and demonstrate that the viruses are able to be neutralized by sera from HIV-infected people or SHIV-infected monkeys.
- 5. Receive, catalog, track, and maintain an inventory of the specimens that arrive for evaluation:
  - a) Advise sample suppliers (Category B contractors) of the most suitable manner for shipment of sera, whole blood, cells or other specimens for evaluation and arrange for the transfer of these specimens from primate laboratories to the Contractor. All shipments must be coordinated so that activity/viability of specimens will not be adversely affected.
  - b) When necessary, pick up or arrange for pick up of incoming specimen shipments from a specified airport or other contact site in a timely manner and assure maintenance of activity and/or viability of the specimens by providing the appropriate temperature in transit from the airport or other contact site to the Contractor's laboratory.
  - c) Receive and catalog specimens arriving for evaluation from the primate laboratories. Maintain documentation on file for all incoming specimens, including but not limited to:primate subject identification number, trial site, protocol identification number, specimen collection date and condition of sample upon arrival.
  - d) Store cataloged, aliquotted specimens under appropriate conditions to retain maximum immunological activity.
  - Maintain specimen tracking and inventory system such that specimens can be traced and located from receipt through processing and assay analysis.

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- 6. Maintain test result database and transfer data electronically:
  - a) Compile and maintain a computerized database of all neutralization assays results, using a format compatible with the FOX-PRO data base that NIAID plans to use to compile records and data from the vaccine studies. Assay results are to be recorded with designations of study protocol number, animal number, specimen collection date, and other information requested by the Project Officer.
  - b) Transfer specified data electronically to the AIDS Vaccine Evaluation Group (AVEG) Statistical and Coordinating Center (SCC) and to the Project Officer at regular intervals as instructed by the Project Officer (format to be agreed upon between NIAID and the Contractor).
  - c) Ensure protection against the loss of data by the duplication of data base files and programs for storage; provide for the security, safety, and accuracy of data on the specimen inventory and the test results database.

#### 7. Provide facilities and resources

- a) Provide facilities and equipment for the work to be conducted, including a biosafety level 2 or 3 laboratory for conducting work with live HIV and SHIV as well as samples from infected monkeys.
- b) Provide, maintain, and operate facilities for controlled storage of sera, virus stocks, cell stocks, and other samples and reagents, including storage at -10 to -20 degrees C, at -70 to -90 degrees C, and in liquid nitrogen conditions, with appropriate monitoring of storage conditions to guarantee continuous proper storage. The reliability of supply systems, electrical power, and backup support systems shall be ensured by the contractor.
- c) Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous materials, including radioactive materials. Specifically, the contractor shall comply with all applicable health and safety regulations while conducting the work set forth herein.
- d) Conduct work under this contract in accordance with all applicable Federal, state, and local laws, codes, ordinances and regulations, and with the following basic references and other related modifications by the Public Health Service:
  - (1) Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for Disease Control and National Institutes of Health, HHS Pub. No. (NIH) 93-8395 published by the U.S. Government Printing Office, third edition, May 1993, stock number 17-040-00523-7.
  - (2) Recommendations for Prevention of HIV Transmission in Health Care Settings, Morbidity and Mortality Weekly Report, Vol. 36, No. 2-S.
  - (3) Agent Summary Statement for Human Immunodeficiency Virus and Report on Laboratory-Acquired Infection with Human Immunodeficiency Virus, Morbidity and Mortality Weekly Report, Vol. 37, No.S-4, pp.1-22.
  - (4) "Guidelines to Prevent Simian Immunodeficiency Virus Infection in Laboratory Workers and Animal Handlers", Morbidity and Mortality Weekly Report, Vol. 37, No. 45, pp. 693-704.
- Designate a project coordinator to manage the day-to-day conduct of the study, to interact with the Category B MAO laboratory or laboratories providing non-human primate samples from the vaccine study or studies, and to provide information on the status of the assay results to the Project Officer.
- 9. Report data and results to NIAID or to a designated NIAID contractor. Printouts of data and verbal reports of the status of the study are to be

provided on an ongoing basis during the course of the study at the request of the Project Officer, in addition to the required periodic (quarterly and final) written reports describing the progress of the study, and in addition to the periodic electronic transfer of data described in item (6) above.

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# SUMMARY OF VACCINE STUDIES FOR WHICH ASSAYS MAY BE REQUIRED

(SECTION A: HUMORAL IMMUNE RESPONSES TO HIV VACCINES)

#### VACCINE STUDY 7

- -----

Title: Evaluation of HIV DNA Vaccines in Monkeys Using the SHIV Model

Description: To compare routes of administration, rhesus monkeys will be immunized by either intramuscular injection or by "gene gun" inoculation with DNA constructs which express HIV-1 env proteins, together with DNA constructs expressing SIV proteins. The animals will be challenged with SHIV to determine if a protective response is induced and, if so, how soon it is induced and how long it persists.

Number of monkeys: 24 (6 groups of 3; 3 groups of 2)

Length of study: 30 months

Number of inoculations per animal: 4 immunizations plus 1 virus challenge

#### **VACCINE STUDY 8**

- -----

Title: Evaluation of the Contribution of SIV Regulatory Genes to the Efficacy of an HIV/SIV DNA Vaccine.

Description: Rhesus monkeys will be immunized intramuscularly with DNA constructs encoding HIV envelope, DNA constructs expressing SIV proteins, and DNA constructs expressing SIV regulatory gene products to determine if theregulatory proteins elicit immune responses (particularly CTL responses) that enhance the ability of the monkeys to resist infection with SHIV.

Number of monkeys: 20 (5 groups of 4)

Length of study: 24 months

Number of inoculations per animal: 4 immunizations plus 1 virus challenge

#### VACCINE STUDY 13

- -----

Title: Immunogenicity of a Soluble Oligomeric Form of the HIV-1 Envelope Protein

Description: Rhesus monkeys will be immunized with a purified oligomeric form of the HIV-1 envelope protein to determine if monkeys will generate antibodies (presumably to conformational epitopes of the oligomeric envelope) that are able to neutralize genetically divergent strains of HIV-1. Vaccines based on monomeric forms of the HIV-1 envelope generate predominantly type-specific

antibodies that neutralize a limited range of HIV-1 isolates, but preliminary studies with the oligomeric form of the envelope indicate that antibodies to it may be more broadly reactive. Animals will be challenged with SHIV after immunization to determine the ability of the immune response to the oligomeric envelope to protect monkeys from infection.

Number of monkeys: 18 (6 groups of 3)

Length of study: 24 months

Number of inoculations per animal: 5 immunizations plus 1 virus challenge

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#### VACCINE STUDY 16

Title: Evaluation of a Recombinant Semliki Forest Virus/HIV Vaccine

Description: Rhesus monkeys will be immunized with an avirulent recombinant Semliki Forest virus expressing HIV-1 envelope and SIV gag proteins. The monkeys will be infected with the virus, which has a broad tissue tropism, by either intramuscular, intravenous, subcutaneous, or mucosal site administration. Animals will be challenged with SHIV to determine the efficacy of this vaccine in protecting from virus infection.

Number of monkeys: 10 (5 groups of 2)

Length of study: 18 months

Number of inoculations per animal: 8 immunizations plus 1 virus challenge

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### SECTION B: HUMORAL IMMUNE RESPONSES TO SIV VACCINES

Independently, and not as an agent of the Government, the Master Agreement Order holder shall provide the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the tasks of the Statement of Work below.

The MAO Contractor shall perform assays to assess the humoral immune responses of macagues that have been immunized with an SIV vaccine. Specifically the MAO Contractor shall:

- 1. Determine the capability of sera or mucosal secretions from monkeys immunized with SIV vaccines to neutralize infection of cell lines and/or primary cells (PBMC) by the SIV strain used for the vaccine. Further characterize these antibodies, including determining the neutralization titer against the vaccine (homologous) SIV strain.
- 2. For sera (or mucosal secretions) that were determined (above) to neutralize the homologous strain of SIV, determine the neutralization titer against infection of T cell lines and/or PBMC by a heterologous strain or strains of SIV.

- Prior to conducting neutralization assays with the monkey sera (or mucosla secretions) from the vaccine studies, grow appropriate SIV virus stocks and demonstrate that the viruses are able to be neutralized by sera from SIV-infected monkeys.
- 4. Receive, catalog, track, and maintain an inventory of the specimens that arrive for evaluation:
  - a) Advise sample suppliers (Category B contractors) of the most suitable manner for shipment of sera, whole blood, cells or other specimens for evaluation and arrange for the transfer of these specimens from primate laboratories to the Contractor. All shipments must be coordinated so that activity/viability of specimens will not be adversely affected.
  - b) When necessary, pick up or arrange for pick up of incoming specimen shipments from a specified airport or other contact site in a timely manner and assure maintenance of activity and/or viability of the specimens by providing the appropriate temperature in transit from the airport or other contact site to the Contractor's laboratory.
  - c) Receive and catalog specimens arriving for evaluation from the primate laboratories. Maintain documentation on file for all incoming specimens, including but not limited to: primate subject identification number, trial site, protocol identification number, specimen collection date and condition of sample upon arrival.
  - d) Store cataloged, aliquotted specimens under appropriate conditions to retain maximum immunological activity.
  - Maintain specimen tracking and inventory system such that specimens can be traced and located from receipt through processing and assay analysis.
- 5. Maintain test result database and transfer data electronically:
  - a) Compile and maintain a computerized database of all neutralization assays results, using a format compatible with the FOX-PRO data base that NIAID plans to use to compile records and data from the vaccine studies. Assay results are to be recorded with designations of study protocol number, animal number, specimen collection date, and other information requested by the Project Officer.
  - b) Transfer specified data electronically to the AIDS Vaccine Evaluation Group (AVEG) Statistical and Coordinating Center (SCC) and to the Project Officer at regular intervals as instructed by the Project Officer (format to be agreed upon between NIAID and the Contractor).

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- c) Ensure protection against the loss of data by the duplication of data base files and programs for storage; provide for the security and safety of data on the specimen inventory and the test results database.
- 6. Provide facilities and resources:
  - a) Provide facilities and equipment for the work to be conducted, including a biosafety level 2 or 3 laboratory for conducting work with live HIV and SHIV as well as samples from infected monkeys.
  - Provide, maintain, and operate facilities for controlled storage of sera, virus stocks, cell stocks, and other samples and reagents,

including storage at -10 to -20 degrees C, at -70 to -90 degrees C, and in liquid nitrogen conditions, with appropriate monitoring of storage conditions to guarantee continuous proper storage. The reliability of supply systems, electrical power, and backup support systems shall be ensured by the contractor.

- c) Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous materials, including radioactive materials. Specifically, the contractor shall comply with all applicable health and safety regulations while conducting the work set forth herein.
- d) The Contractor shall conduct work under this contract in accordance with all applicable Federal, state, and local laws, codes, ordinances and regulations, and with the following basic references and other related modifications by the Public Health Service:
  - (1) Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for Disease Control and National Institutes of Health, HHS Pub. No. (NIH) 93-8395 published by the U.S. Government Printing Office, third edition, May 1993, stock number 17-040-00523-7.
  - (2) Recommendations for Prevention of HIV Transmission in Health Care Settings, Morbidity and Mortality Weekly Report, Vol. 36, No. 2-S.
  - (3) Agent Summary Statement for Human Immunodeficiency Virus and Report on Laboratory-Acquired Infection with Human Immunodeficiency Virus, Morbidity and Mortality Weekly Report, Vol. 37, No.S-4, pp.1-22.
  - (4) "Guidelines to Prevent Simian Immunodeficiency Virus Infection in Laboratory Workers and Animal Handlers," Morbidity and Mortality Weekly Report, Vol. 37, No. 45, pp. 693-704.
- 7. Designate a project coordinator to manage the day-to-day conduct of the study, to interact with the Category B MAO laboratory or laboratories providing non-human primate samples from the vaccine study or studies, and to provide information on the status of the assay results to the Project Officer.
- 8. Report data and results to NIAID or to a designated NIAID contractor. Printouts of data and verbal reports of the status of the study are to be provided on an ongoing basis during the course of the study at the request of the Project Officer, in addition to the required periodic (quarterly and final) written reports describing the progress of the study, and in addition to the periodic electronic transfer of data described in item (6) above.

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SUMMARY OF VACCINE STUDIES FOR WHICH ASSAYS MAY BE REQUIRED:

- -----

(SECTION B: HUMORAL IMMUNE RESPONSES TO SIV VACCINES)

VACCINE STUDY 1

- -----

Title: Comparison of Different Routes of Immunization with ALVAC/SIV

Description: Rhesus monkeys will be immunized by three different routes with recombinant avipox (ALVAC) expressing SIV genes. Intramuscular and two mucosal

routes are planned. Animals will be challenged with SIV administered intravenously or at a mucosal surface to determine if there is a difference in efficacy of the vaccine when administered by different routes and to determine if mucosal routes of immunization are more effective at blocking infection at mucosal surfaces than intramuscular immunizations. Monkeys will be followed after challenge to determine whether infection has occurred and whether immunization affects disease progression in any infected animals.

Number of monkeys: 48 (8 groups of 6)

Length of study: 32 months

Number of inoculations per animal: 5 immunizations plus 1 virus challenge

#### **VACCINE STUDY 2**

- -----

Title: Comparison of Different Routes of Immunization with NYVAC/SIV

Description: Rhesus monkeys will be immunized by three different routes with recombinant attenuated vaccinia virus (NYVAC) expressing SIV proteins. Intramuscular and two different mucosal routes are planned. Animals will be challenged with SIV administered intravenously or at a mucosal surface to determine if there is a difference in efficacy of the vaccine when administered by different routes and to determine if mucosal routes of immunization are more effective at blocking infection at mucosal surfaces than intramuscular immunizations. Monkeys will be followed after challenge to determine whether infection has occurred and whether immunization affects disease progression in infected animals.

Number of monkeys: 48 (8 groups of 6)

Length of study: 32 months

Number of inoculations per animal: 5 immunizations plus 1 virus challenge

#### VACCINE STUDY 5

- -----

Title: Evaluation of Immunization with Recombinant Vaccinia/SIV Vaccine Followed by Immunization with SIV Proteins

Description: Rhesus monkeys will be immunized with recombinant vaccinia expressing SIV genes by intradermal, subcutaneous, intramuscular or oral routes, followed by immunizations with SIV proteins. Animals will be challenged WITH SIV to determine whether the efficacy of the vaccine is affected by the route of administration.

Number of monkeys: 24 (4 groups of 6)

Length of study: 24 months

Number of inoculations per animal: 6 immunizations plus 1 virus challenge

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## VACCINE STUDY 14

- -----

Title: Evaluation of recombinant BCG/SIV vaccines

Description: Rhesus monkeys will be immunized orally with a live recombinant BCG expressing SIV proteins, followed by immunization with a mixture of SIV peptides. The monkeys will be challenged with SIV administered intravenously or

at a mucosal site different from the site of immunization to determine if the live recombinant BCG vaccine administered by a mucosal route confers protection from infection.

Number of monkeys: 16 (4 groups of 4)

Length of study: 30 months

Number of inoculations per animal: 4 immunizations plus 1 virus challenge

#### **VACCINE STUDY 15**

- -----

Title: Evaluation of a Recombinant Polio/SIV Vaccine

Description: Pig-tailed macaques will be immunized at two mucosal sites with live recombinant poliovirus replicons expressing SIV proteins. This will be followed by immunization with purified SIV proteins. The animals will be challenged with SIV either intravenously or at a mucosal site used for immunization or at a mucosal site different from the one used for immunization.

Number of monkeys: 30 (for immunizations: 6 groups of 4; for titration of

challenge virus stock: 6)

Length of study: 24 months

Number of inoculations per animal: 3 immunizations plus 1 virus challenge

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2.1

#### AGREEMENT

WHEREAS, Ajinomoto Co., Inc. ("Ajinomoto") of Tokyo, Japan desires to sponsor and fund a research and development program and BTRL Contracts and Services, Inc., doing business as Biotech Research Laboratories (BTRL) a wholly owned subsidiary company of Boston Biomedica, Inc., desires to provide the necessary services to perform such research (The Project), this Contract Agreement is made this 1st day of October 1995 by Ajinomoto and BTRL. In consideration of the mutual promises set forth herein, the parties hereto state and agree as follows:

- 1. BTRL agrees, that in return for the payments to be made thereunder, it shall provide services including labor, materials and supplies, facilities and administrative support necessary to perform the Project as described in Attachment I, using its best efforts therein. This work will be performed under the direction of the Project Officer (Ajinomoto) and facilitated by a Principal Investigator (BTRL).
- In consideration of the services to be performed by BTRL during the Project, Ajinomoto will pay BTRL in accordance with the budget specified in Attachment II.
  - a. The Labor, Materials and Supplies and Other Direct Charges will reflect the actual usage on the Contract, and will be burdened with a [Language Deleted Due To Confidential Treatment Request.] Fringe Benefit Rate, an [Language Deleted Due To Confidential Treatment Request.] G&A Rate and a [Language Deleted Due To Confidential Treatment Request.] Fee as indicated. Fringe benefits will include: long-term disability, life insurance, earned time, tuition reimbursement, usually ten paid holidays, 401K plan and short term disability. No health insurance coverage will be offered to this class of employee ("Project At-Will").
  - b. The Rental and Other Fixed Overhead Costs will remain fixed in the course of the Project as indicated.
  - c. Any required equipment purchases which are not billed directly to this contract, but which come from a Supplementary Budget, will not be burdened with G&A or Fee.

The payments on each year's budget shall be payable in two equal semi-annual installments, the first of which shall be due as of the effective date of this Agreement and the remaining installments due at six month intervals thereafter. BTRL will provide Ajinomoto with monthly statements indicating the actual expenditures incurred on this Project.

In the event that substantial changes in the proposed budget are requested by Ajinomoto, (such as hiring additional personnel or requiring substantial increases in the cost of Materials or Services), and such changes will exceed the proposed

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budget for the year, BTRL will request a Supplementary Budget and await Ajinomoto's approval prior to incurring these costs. Approved payments relating to the Supplementary Budget will be made in accordance with the manner detailed in a., b., c., above.

3. BTRL agrees that in the performance of the Project, it shall provide the personnel identified and required by Ajinomoto. Initially, this personnel shall consist of a Principal Investigator (10% effort), two full-time Technicians and one full-time Administrative Assistant. If requested by Ajinomoto, a full-time Senior Scientist or other personnel may be added at a subsequent time. Personnel hired by BTRL for the Project, other than the P.I., will be "Project At-Will" employees directly reimbursed by the

Project. The scientific personnel working on the Project shall have the necessary scientific training and experience to perform the Project.

- 4. In further consideration of the payments to be made in Paragraph 2 above, BTRL shall provide two carpeted offices (designated as Room I and Ia on BTRL's floor plan), one for Dr Aoki, the on-site Project Officer employed by Ajinomoto, and another for the Administrative Assistant and scientific personnel. The offices will come equipped with a telephone extension connecting to the Company switchboard for internal and local use and a computer network connection. Private telephone line(s) will be provided by the Project as will any additional office improvements. BTRL also agrees to provide to the Project, laboratory space designated as Laboratory X and Xa on BTRL's floor plan. Laboratory Xa comes equipped with laboratory casework and cabinets. Laboratory X does not come equipped with laboratory casework or cabinets. Any additional casework, cabinets or laboratory renovations will be provided by the Project.
- 5. Ajinomoto agrees and shall require the Project Officer and any other Ajinomoto representative entering BTRL's premises to agree to the following:
  - a. The presence of such person(s) in BTRL's premises is for the benefit of Ajinomoto and though BTRL will use reasonable efforts to maintain its premises in a safe condition, BTRL shall not be liable for any illness or injury suffered by such person(s) while in, on or around BTRL's premises, including its laboratories where infectious biological materials are or may be used.
  - b. In the event of any illness or injury to such person(s) occurring on, in or around BTRL's premises, BTRL shall be released from any and all responsibility or liability for such illness or injury except to the extent such illness or injury occurred as a result of any intentional misconduct by BTRL. Ajinomoto shall defend BTRL against any such claims by such persons and indemnify BTRL from any liability arising from such claims.

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- c. Ajinomoto shall have the responsibility of providing statutory workers compensation insurance and any other insurance coverage that may apply to such person(s).
- d. BTRL shall have no obligation to provide any insurance coverage whatsoever for the benefit of Ajinomoto or such person(s).
- e. Such person(s) shall abide by all BTRL policies and procedures, including those concerning health, security and safety, and any violation of such policies and procedures shall entitle BTRL to refuse to allow such person(s) on its premises and/or to require Ajinomoto to substitute other representatives for those who violate such policies and procedures.
- f. Any non-public information learned about any aspect of the business of BTRL and/or its affiliated companies (other than information concerning the Project) shall be held in full and complete confidence and shall not be used, or disclosed to any person or entity whatsoever, without the prior written consent of BTRL. The foregoing restriction shall apply to technical information, and financial and non-financial information including but not limited to know-how, formulae, patents, processes, procedures, sales information, manufacturing data and names of customers or vendors.
- 6. This Agreement and the Project shall extend for an initial term of three (3) years, which may be extended by mutual agreement for additional terms of one year each.

Ajinomoto shall have the right to terminate this Agreement prior to September 30, 1998 by giving three (3) months prior written notice to BTRL. If however, Ajinomoto terminates this Agreement without cause for its own convenience BTRL shall be due the balance of all Fee as specified

in the Project Budget (Attachment II). Except as otherwise provided above or unless explicitly agreed otherwise between the parties, neither party shall have the right to terminate this Agreement on or before October 30, 1998, except that either party may terminate this Agreement forthwith:

- a. in the event the other party shall breach any of its obligations under this Agreement and fails to remedy such breach within sixty (60) days from receipt of notice of such breach by the party not in default:
- in case of the other party's liquidation, bankruptcy or state of insolvency; or
- c. in the event the other party assigns this Agreement without the written consent of the terminating party.

Upon expiration or termination of this agreement for any reason whatsoever, all claims each party may have against the other party shall become due. The parties

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shall make up a list of such claims of each against the other. Such claims shall be offset and the net amount arrived at shall be settled within sixty (60) days from the termination of this agreement.

- 7. In order to protect the confidentiality of all confidential subject matter, the parties agree not to disclose or release such confidential subject matter to any person, laboratory, institution, corporation or other entity that is not directly participating in this Project; and, to not use or permit the use of said confidential subject matter for any purpose other than for the Project without first obtaining the express written permission of the other party, except under the following circumstances:
  - a. Subject matter that, as of the signing of this agreement, is in the public domain;
  - Subject matter that, as of the date of the signing of this agreement, can be shown by written evidence to have been known to either party;
  - c. Subject matter that, at any time is received in good faith by either party from a third party who was lawfully in possession of the same and had the right to disclose the same; and
  - Subject matter that the parties mutually agree in writing to release from the terms of this agreement.
- Any and all discoveries and/or inventions arising from performance of the Project shall belong to Ajinomoto. BTRL shall, however, be entitled to a royalty of [Language Deleted Due To Confidential Treatment Request.] of the net sales of those products which are covered by a product patent arising out of the Project; and BTRL shall be entitled to a royalty of [Language Deleted Due To Confidential Treatment Request.] of the net sales of products covered by only a process patent arising from the Project. In the event a product is covered by both a product patent and a process patent, BTRL shall receive a royalty of [Language Deleted Due To Confidential Treatment Request.]. Royalty payments on products covered by patents shall continue for the life of the applicable patent. BTRL shall be entitled to a [Language Deleted Due To Confidential Treatment Request.] royalty on net sales of products utilizing technology developed under the Project if there is no patent on either the product or the process utilized therein. Royalty payments applicable to unpatented products or processes shall continue for a period of ten years from the date of the first commercial sale of a product utilizing the unpatented technology.
- BTRL shall have a right of first refusal on an exclusive or semi-exclusive (with Ajinomoto) basis in the event Ajinomoto decides to license any patented technology arising from the Project. BTRL shall have

the right to use unpatented technology in exchange for payment of a sum to be agreed upon by both parties during the term of its use; however, after ten years of royalty payments BTRL shall be deemed to have a paid up license to use such technology.

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- 10. In the event that either of the parties hereto, at any time during the term of this Agreement, commits a breach of any provision thereunder, and fails to rectify such breach within sixty (60) days from the receipt of written notice thereof from the other party, such other party may be entailed to terminate this Agreement.
- 11. In the event of any dispute, the parties shall use their best efforts to resolve such dispute. If such dispute is not resolved within sixty (60) days of the first written notice thereof, either party may request arbitration, with such arbitration to take place in Rockville, Maryland, in accordance with the Commercial Mediation rules of the American Arbitration Association. The parties agree that they will be represented at the oral proceedings of such mediation by at least one of their authorized officers who may be assisted by one or more advisors. The cost of such mediation shall be shared equally by the parties, and each party shall bear its own expenses in connection with such mediation. The parties shall endeavor and shall instruct the mediator to have the mediation proceedings completed and a final resolution reached within 60 days of the date the mediator is appointed.

This Agreement shall be governed by and construed in accordance with the laws of the State of Maryland. In the event of an unsettled dispute, the parties mutually agree to the use of any federal or state court in the State of Maryland having jurisdiction over the subject matter thereof, and the parties hereby waive any and all rights to object to the laying of venue in any such court and to the right to claim that any such court may be an inconvenient forum. The parties hereby submit themselves to the jurisdiction of each such court and agree that service of process on them in any such action may be effected by notice in writing to the officials or their replacements who have signed this Agreement.

- 12. In the event of termination of or at the end of the Agreement Ajinomoto agrees to reimburse BTRL for those expenses incurred by the Project after the winding down of the Project. Sixty days prior to the end of the agreement BTRL will submit to the on-site Project Officer a list of expenses to be approved that will be incurred as a result of the end of the project
- 13. Attachment I is a description of the Project.
- 14. Attachment II is the Project Budget.

Managing Director

- 15. Attachment III is the List of Equipment.
- 16. Attachment IV is a Building Floor Plan designating office and laboratory space to be assigned to the Project.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date set forth above by their duly authorized representatives.

AJINOMOTO CO., INC	. BTRL CONTRACTS AND SERVICES, INC.
BY	BY
Masakatsu Nakamura	Richard T. Schumacher
TITLE	TITLE

President

#### ATTACHMENT 1

#### Research Objectives

 Relationship between immunodeficiency and plasma levels of L-cystine

There is evidence to support the idea that persons with immunodeficiencies, such as Low Natural Killer Syndrome (LNKS), advanced and terminal stage cancers, HIV-1 infections, etc., have significantly lower plasma levels of certain essential amino acids, i.e., L-cystine and L-glutamine compared to those of healthy individuals. Since current assays for immunodeficiencies, specifically NK activity assays, require the use of radioisotopes and viable biological samples, a chemical assay to measure amino acids would be both simpler and easier. Our group is developing a colorimetric assay to determine plasma levels of L-cystine. This assay can be used in place of the more time-consuming NK activity assay to determine a person's immune status. The results we have obtained thus far using this colorimetric assay lend further support to the above hypothesis.

The ultimate goal of this project is to develop a diagnostic kit that makes use of plasma levels of L-cystine as a marker for immunodeficiency.

 Support of clinical trials of Low NK Syndrome patients by treatment with Lentinan.

The University of Pittsburgh School of Medicine, in cooperation with Ajinomoto Company, is planning clinical trials to gain FDA approval to administer Lentinan, a polysaccharide extracted from an edible Japanese mushroom, to patients with Chronic Fatigue Syndrome (CFS) with or without LNKS. Use of Lentinan in Japan has proven to be an effective immunopotentiator for the treatment of CFS and LNKS.

c. Examination of etiology of Low NK Syndrome

Our group will also be collaborating with the University of Pittsburgh School of Medicine to determine the etiology of LNKS. As of now, there are three hypotheses as to the cause of LNKS: (1) an undetermined virus, (2) a defective metabolic pathway and/or (3) a genetic factor. Once the mechanism(s) that leads to LNKS has been defined, a quantitative assay, e.g., PCR in the case of a viral infection, can be utilized to further characterize the etiologic agent(s).

ATTACHMENT II YEARLY COST BREAKDOWN

# SUMMARY OF ANNUAL COSTS AJINOMOTO CONTRACT

3 YEAR YEAR 1 YEAR 2 YEAR 3 TOTAL

#### DIRECT LABOR

Technician B. Thompson [Language Deleted Due To Confidential Treatment Request.] Technician H. Tissue

Admin Asst. R.L. East [Language Deleted Due To Confidential Treatment Request.] P.I. Manak

## TOTAL DIRECT

LABOR [Language Deleted Due To Confidential Treatment Request.]

FRINGE BENEFITS

**FACILITIES** 

OFFICE 272 SQUARE FT. [Language Deleted Due To Confidential Treatment Request.] LABS 892 SQUARE FT.

OTHER FIXED OVERHEAD COSTS

MATERIALS [Language Deleted Due To Confidential Treatment Request.]

OTHER DIRECT

(HEALTH INSURANCE, POSTAGE, TRAVEL, PRIVATE TELEPHONE)

**SUBTOTAL** 

G & A [Language Deleted Due To Confidential Treatment Request.]

TOTAL COSTS

[Language Deleted Due To Confidential Treatment Request.]

**FEE** 

TOTAL COSTS PLUS

FIXED FEE [Language Deleted Due To Confidential Treatment Request.]

**EQUIPMENT** 

DIRECT LABOR BASED ON 1856 PERON HOURS PER YEAR

#### ATTACHMENT III

#### FURNITURE/COMPUTER EQUIPMENT:

Ajinomoto owns desks, chairs, and file cabinets for Dr. Aoki and his staff; 2 IBM compatible computers, 1 laser printer, and 1 laserjet fax.

**EQUIPMENT:** 

Ajinomoto owns the following equipment:

Miscellaneous equipment, supplies, disposable labware, chemicals, etc.

Locker

Scotsman Ice Maker

LKB Ultraspec Plus (Spectrophotometer)

Perkin Elmer Thermal Cycler (Gene Amp PCR System 9600)

Sorvall RT6000B Refrigerated Centrifuge

Ohaus balance

3x Forma Scientific Water-Jacketed Incubator

2x Olympus CK2 Microscopes

Olympus CK2 Microscope with Camera

Zeiss Axiophot Fluorescence Microscope

Skatron A/S Plate Washer

HPLC equipment

Branson 8200 Sonifier

Orion Research pH meter

Sartorius Balance

Ohaus GT480 Balance

2x Refrigerator/Freezers

Beckman 18-70M Ultracentrifuge

Revco (-70%C) freezer (Deep Freezer)

Napco 201 and 202 water baths

Beckman Microfuge 12

Power Supply

Fischer Biotech UV Box

HP Quiet Jet Printer

Titertek Multiskan Mcc/340 Plate Reader

Mistral 3000E Centrifuge

Beckman J2-M1 Centrifuge

Fire Safety Cabinet

Hoeffer Transfor

Packard Liquid Scintillation Analyzer

Branson Sonifier 250

LKB-HPLC Variable Monitor

LKB-HPLC Superac LKB-HPLC LC Controller LKB-HPLC HPLC Pump

Attachment IV

[FLOOR PLAN -- UPPER LEVEL]

Attachment IV

[FLOOR PLAN -- LOWER LEVEL]

# EXHIBIT 10.7 LEASE AGREEMENT

THIS LEASE is made as of this 30th day of June, 1992, by and between (i) Cambridge Biotech Corporation, a Delaware corporation qualified to do business in the State of Maryland (the "Landlord"), with a business and mailing address of 1500 East Gude Drive, Rockville, MD 20850, and (ii) BTRL Contracts and Services Inc., a Massachusetts corporation qualified to do business in the State of Maryland (the "Tenant"), with a business and mailing address of c/o Boston Biomedica, Inc., 375 West Street, West Bridgewater, Massachusetts 02379.

## WITNESSETH:

For and in consideration of the covenants herein contained and upon the terms and conditions herein set forth, the parties agree as follows:

- 1. Introductory Provisions.
- (a) Fundamental Lease Provisions. Certain Fundamental Lease provisions are presented in this Section in summary form solely to facilitate convenient reference by the parties hereto:

convenien	is reference by the parties her	<b>C</b> 10.		
<table></table>	<c> <c> <c (1)="" leased="" premises<="" td=""><td>3 Taft Court</td><td><c> [See Section and Exhibit A]</c></td><td>2(a)</td></c></c></c>	3 Taft Court	<c> [See Section and Exhibit A]</c>	2(a)
	Rockville, MD 20850 (2) Floor Space of Leased 20,680 square feet Premises (more or less)			
	(3) Gross Leasable Area of Property	22,680 square f	eet [See Sec	tion 2(b))
	<ul><li>(4) A. Proportionate Share</li><li>B. R.E. Proportionate</li><li>Share</li><li>C. Insurance Proportionate Share</li></ul>	91% 67% 67%	[See Section 2	2(c)]
	(5) Rent Commencement Date July 1, 1992		[See Se	ction 3(a)]
	(6) Expiration Data	June 30, 1997	[See Section	3(a)]
	(7) Minimum Annual Rent  1 2 3 4 5	Lease Year \$19,200.00 \$144,760.00 \$206,800.00 \$248,160.00 \$289,520.00	Minimum Annual Rent	[See Section 4(a)]
	(8) Basic Monthly Rent  1 2 3 4 5	Lease Year \$1,600.00 \$12,063.33 \$17,233.33 \$20,680.00 \$24,126.66	Basic Monthly Rent [Se	ee Section 4(a)]
	and m (as all- zoning biotech	General office, th/development, nanufacturing owed by code) in nnology and dical fields	[See Section 6]	
	(10) Security Deposit	\$12,063.00	[See Section	5]
	(11) Leasing Broker	None	[See Section 35	]

</TABLE>

<sup>(</sup>b) References and Conflicts. References appearing in Section 1(a) are intended to designate some of the other places in the Lease where

additional provisions applicable to the particular fundamental Lease provisions appear. These references are for convenience only and shall not be deemed all inclusive. Each reference in this Lease to any of the fundamental Lease provisions contained in Section 1(a) shall be construed to incorporate all of the terms provided for under such provisions, and such provisions shall be read in conjunction with all other provisions of this Lease applicable thereto. If there is any conflict between any of the fundamental Lease provisions set forth in Section 1(a) and any other provisions of the Lease, the latter shall control.

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(c) Exhibits. The following drawings and special provisions are attached hereto as exhibits and hereby made a part of this Lease:

Exhibit A. Site Plan of Property including the Leased Premises and Adjacent Laboratory Building

Exhibit B. List of Landlord Repairs After Rent Commencement Date Exhibit C. Rules and Regulations

#### 2. Premises.

- (a) Leased Premises. Landlord hereby leases to Tenant, and Tenant hereby rents from Landlord, that certain building (the "Leased Premises") which is located at 3 Taft Court, Rockville, MD 20850 and is outlined in blue on Exhibit A, together with the non-exclusive right to use the common areas of the Property as more fully described in Section 7 hereof. The Leased Premises shall consist of the agreed square footage of floor space as specified in Section 1(a)(2).
- (b) The Property. The Leased Premises is a part of a parcel of improved real property owned by Landlord which is more fully described as "Lot 5, Block A, in the Redgate Industrial Park Subdivision as shown on a plat thereof recorded in Plat Book 102, Plat 11503 among the Land Records of Montgomery County, Maryland" (the "Property"). Landlord represents and warrants to Tenant that it is the owner in fee simple of the Property, subject to certain encumbrances, rights of way, easements, and other matters of record. Located on the Property is the Leased Premises, a laboratory building known as 3 1/2 Taft Court, Rockville, Maryland 20850 (the "Adjacent Laboratory Building"), and certain common areas as hereinafter defined in Section 7. Landlord and Tenant acknowledge that the gross leasable area of both the Leased Premises and the Adjacent Laboratory Building is specified in Section l(a)(3) ("Gross Leasable Area" or "GLA"), and shall hereafter be referred to as the GLA of the Property. The GLA of the Property shall be used hereinafter for purposes of computing Tenant's "Proportionate Share" (as hereinafter defined) of certain expenses payable to Landlord as "Additional Rent" (as hereinafter defined). Landlord reserves the right to modify the GLA of the Property, and shall modify the GLA of the Property, from time to time during the Lease Term as a result of construction of new leasable improvements or the demolition of existing leasable improvements on the Property. Landlord's right to modify the GLA of the Property shall not be construed to provide Landlord with any right to modify the GLA of the Leased Premises, or to deprive Tenant of the reasonable use of any portion of the parking areas allocated to it.
- (c) Tenant's Proportionate Share. Tenant's Proportionate Share of certain expenses hereinafter made payable to Landlord as Additional Rent is specified in Section 1(a)(4). Said computation is based upon the ratio of the total area of floor space in the Leased Premises to the GLA of the Property. The Proportionate Share shall be modified during the Lease Term in the event that the GLA of the Property is modified as described in Section 2(b) above.

## 3. Term and Acceptance by Tenant.

(a) Lease Term. The term of this Lease (sometimes herein called the "Lease Term") shall begin as of the date specified in Section 1(a) (5)

("Rent Commencement Date") and, unless sooner terminated as herein provided, continue thereafter through the date specified in Section l(a)(6) ("Expiration Date"). The period commencing with the Rent Commencement Date and ending on the last day of the twelfth (12th) full calendar month thereafter shall constitute the first "Lease Year" as such

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term is used herein. Each successive full twelve (12) month period during the Lease Term shall constitute a "Lease Year".

- (b) Acceptance of Leased Premises. Tenant accepts possession of the Leased Premises in "as is" condition, except that Landlord shall be obligated to complete, or cause to be completed, repairs to the Leased Premises which are identified in Exhibit B, in a good and workmanlike manner using first quality materials, on or before the ninetieth (90th) day following the date of execution of this Lease by both parties hereto. Landlord shall use all reasonable efforts to cause said repair work to be completed by such independent contractors in a diligent manner. Tenant expressly acknowledges and agrees that Landlord has made no representations or warranties with respect to the Leased Premises, and that no promises to alter, repair or improve the Leased Premises or the Property have been made by Landlord or its agents or employees, unless specifically set forth herein.
- (c) Permits. Tenant shall be responsible for obtaining the occupancy permit (if and to the extent required by law) and all other permits or licenses necessary for its lawful occupancy of the Leased Premises. This requirement shall not relieve Tenant of its liability for the payment of Minimum Annual Rent and Additional Rent, and the performance of all other obligations contained herein, from and after the Rent Commencement Date, in the event that all of said approvals, permits and licenses have not been acquired prior thereto.

# 4. Rent.

(a) Minimum Annual Rent. The Minimum Annual Rent reserved hereunder in Section 1(a)(7) shall be payable by Tenant to Landlord during each Lease Year of the Lease Term in equal monthly installments of Basic Monthly Rent in the amounts set forth in Section 1(a)(8), due in advance, without notice or demand, and without set-off, deduction, recoupment or abatement of any kind, on the Rent Commencement Date and the first (1st) day of each and every calendar month thereafter during the Lease Term. In the event that the Rent Commencement Date occurs on a day other than the first day of a calendar month or the Lease Term ends on a day other than the last day of a calendar month, then the Basic Monthly Rent or Additional Rent for such partial month(s) shall be computed on a per diem basis by dividing the Basic Monthly Rent or Additional Rent by thirty (30) and multiplying it by the number of days in the partial calendar month. Rent shall be paid to Landlord, or to such other person(s), or at such other address as Landlord may designate to Tenant from time to time.

## (b) Additional Rent.

- (i) General. Whenever it is provided by the terms of this
  Lease that Tenant is required to make any payment to Landlord other than a
  payment of Minimum Annual Rent, such payment shall be deemed to be a payment of
  additional rent ("Additional Rent"). Unless otherwise expressly specified
  herein, Additional Rent shall be paid by Tenant with the next installment of
  Basic Monthly Rent thereafter falling due. Additional Rent shall include, but
  not be limited to:
- (ii) Real Estate Taxes. On or before September 1, 1992, Tenant shall pay to Landlord its R.E. Proportionate Share of the Real Estate Taxes to be incurred by Landlord on the Property during the 1992-1993 tax year, based upon a copy of the 1992-1993 tax bill for the Property delivered to Tenant

by Landlord prior thereto (or if a copy of said tax bill is not delivered to Tenant until after September 1, 1992, then within five (5) business days of the receipt thereof). Commencing upon the 1st day of October, 1992, and thereafter on the first day of each calendar month throughout the Lease Term, Tenant shall pay to Landlord, without

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notice or demand therefor (other than the annual notice of Landlord's estimate of Tenant's R.E. Proportionate Share of the Real Estate Taxes and a copy of the tax bill as described in the following paragraph of this Section), and without any deduction whatsoever, one-twelfth (1/12) of its R.E. Proportionate Share of Landlord's good faith estimate of the Real Estate Taxes to be incurred by Landlord on the Property during the following tax year (prorated, if necessary, if the remainder of the Lease Term constitutes less than the full tax year). Tenant's obligation to pay its R.E. Proportionate Share of the Real Estate Taxes incurred during the Lease Term shall survive the expiration or other termination of the Lease.

The term "Real Estate Taxes" shall mean all taxes and assessments, general and special, ordinary and extraordinary, foreseen and unforeseen, now or hereafter assessed, levied or imposed upon the Property, including both the land and the improvements which are built thereon, including, without limitation, front foot benefit charges and adequate public facility costs and assessments, together with (i) any tax, assessment, or other imposition in the nature of a real estate tax, (ii) any ad valorem tax on rent or any tax on income if imposed in lieu of or in addition to real estate taxes and assessments, and (iii) any taxes and assessments which may hereafter be substituted for real estate taxes, including by way of illustration only, any tax, assessment or other imposition (whether a business rental or other tax) now or hereafter levied upon Landlord for a tenant's use or occupancy of or conduct of business on the Property, or a tenant's improvements to or furniture, fixtures or equipment on the Property. Real Estate Taxes shall also include all reasonable costs incurred by Landlord in contesting the validity or amount of any such taxes. Real Estate Taxes shall not include transfer, inheritance, capital stock or income taxes or other similar personal tax of Landlord, nor any late charges, penalties or interest, incurred due to untimely payments by Landlord in connection with said tax.

Within fifteen (15) days after Landlord's receipt from the taxing authority of the Real Estate Tax bill for the 1993-1994 tax year and for each tax year thereafter during the Lease Term, Landlord shall deliver to Tenant a copy of such tax bill, together with a statement showing Tenant's R.E. Proportionate Share of the actual Real Estate Taxes due for said tax year and the amount of payments made by Tenant based upon the estimate thereof. Tenant shall pay Landlord, within thirty (30) days of Tenant's receipt of such statement, Tenant's R.E. Proportionate Share of the excess, if any, of the Real Estate Taxes for such tax year over the estimated costs thereof. If the amount paid by Tenant as Tenant's R.E. Proportionate Share of the estimated Real Estate Taxes for such tax year exceeded Tenant's R.E. Proportionate Share of actual Real Estate Taxes for such tax year, the excess shall be credited toward payment of the next installment of Basic Monthly Rent to be paid by Tenant after Tenant receives said statement from Landlord. If the amount paid by Tenant for the last tax year of the Lease Term exceeds Tenant's R.E. Proportionate Share of actual Real Estate Taxes for such tax year, Landlord shall pay Tenant the excess amount within thirty (30) days after Landlord's submission to Tenant of the aforesaid statement for such tax year.

In the event that the Adjacent Laboratory Building is demolished during the Lease Term, then, commencing upon the effective date of the reassessment of the Property and the modification of Real Estate Taxes resulting from such demolition, and for so long as the Leased Premises constitutes one hundred percent (100%) of the leasable improvements located on the Property, Tenant shall be obligated to pay Tenant's R.E. Proportionate Share of the Real Estate Taxes assessed against the Property land and one hundred percent (100%)

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Upon Tenant's written request, Landlord will contest, at Tenant's expense, the validity or amount of any such Real Estate Tax. Tenant shall be entitled to its R.E. Proportionate Share of any refund.

Landlord shall deposit and thereafter hold in escrow, until disbursement, the funds received from Tenant pursuant to this section in an interest bearing, federally insured account. All interest earned on said account shall be credited to Tenant and shall be used in the adjustments to Tenant's payments made hereunder from time to time during the Lease Term so that Landlord collects only such monies as are necessary to pay Tenant's R.E. Proportionate Share of said Real Estate Taxes.

In addition to Tenant's obligation for the payment of its R.E. Proportionate Share of the Real Estate Taxes, Tenant shall be liable for, and shall pay before delinquency, all taxes levied against any personal property or trade fixtures placed by Tenant in or about the Leased Premises.

(iii) Insurance. Commencing upon the Rent Commencement Date and thereafter throughout the Lease Term, Tenant shall pay to Landlord without notice or demand therefor and without any deduction whatsoever, its Insurance Proportionate Share of the premium cost of the casualty insurance, liability insurance, rent loss insurance, and other reasonable and necessary form of insurance carried by Landlord with respect to the Property ("Insurance Cost") during any policy year; provided, however, that if the Adjacent Laboratory Building is demolished during the Lease Term, then commencing upon such demolition and for so long as the Leased Premises constitutes one hundred percent (100%) of the leasable improvements on the Property, Tenant shall be obligated to pay one hundred percent (100%) of the Insurance Cost.

Not less than ten (10) days before the Rent Commencement Date, Landlord shall deliver to Tenant a written statement of Landlord's estimate of the amount of the Insurance Cost for the then-current policy year, and Tenant's Insurance Proportionate Share of such Insurance Cost. On the Rent Commencement Date, and on the first day of each month thereafter throughout the Lease Term, Tenant shall pay one-twelfth (1/12) of Tenant's Insurance Proportionate Share of Landlord's estimate of the Insurance Cost for the then-current policy year, as shown on Landlord's estimate. Landlord shall submit its estimate of the Insurance Cost for the forthcoming policy year and Tenant's Insurance Proportionate Share thereof at the commencement of each such policy year, and Tenant's monthly payments made after its receipt of such estimate shall be in the amount of one-twelfth (1/12) of the amount of Tenant's Insurance Proportionate Share of Insurance Cost as shown on such estimate. Landlord may revise its estimate of the Insurance Cost at any time during a policy year by notice to Tenant, setting forth such revised estimate and Tenant's Insurance Proportionate Share thereof. In such event, all monthly payments made by Tenant after such notice shall be in an amount calculated on the basis of such revised estimate. Tenant shall, in all cases, continue to make monthly payments of Insurance Cost based on the last estimate received from Landlord until it receives a revised or updated estimate.

After the end of each policy year, Landlord will as soon as practicable submit to Tenant a statement of the actual Insurance Cost for such policy year and Tenant's Insurance Proportionate Share thereof. Landlord shall cause its insurance carrier, whenever practical, to issue policies of insurance covering the Leased Premises which are separate and apart from the Adjacent Laboratory Building and all other properties owned by Landlord, in which event Tenant's Proportionate Share of Insurance Cost shall be the full cost payable pursuant to said

separate policy. Where such separate policies cannot be issued practically, Landlord shall cause its insurance carrier to provide a written statement identifying the manner in which all premiums paid by Landlord are allocated to reflect the portion thereof attributable to the insurance carried on the Leased Premises and the portion thereof attributable to the insurance carried on the Adjacent Laboratory Building and other properties owned by Landlord. Tenant shall pay Landlord, within thirty (30) days of Tenant's receipt of such statement, Tenant's Insurance Proportionate Share of the excess, if any, of Insurance Cost for such policy year over the projected Insurance Cost. If the amount paid by Tenant as Tenant's Insurance Proportionate Share of the estimated Insurance Cost for such policy year exceeded Tenant's Insurance Proportionate Share of actual Insurance Cost for such policy year, the excess shall be credited toward payment of the next installment of Basic Monthly Rent to be paid by Tenant after Tenant receives said statement from Landlord. If the amount paid by Tenant for the last policy year of the Lease Term exceeds Tenant's Insurance Proportionate Share of actual Insurance Cost for such year, Landlord shall pay Tenant the excess amount within thirty (30) days after Landlord's submission to Tenant of the aforesaid Insurance Cost statement for such policy year.

Landlord shall deposit and thereafter hold in escrow, until disbursement, the funds received from Tenant pursuant to this section in an interest bearing, federally insured account. All interest earned on said account shall be credited to Tenant and shall be used in the adjustments to Tenant's payments made hereunder from time to time during the Lease Term so that Landlord collects only such monies as are necessary to pay Tenant's Insurance Proportionate Share of said Insurance Cost.

Landlord agrees that, at all times during the Lease Term, it shall carry casualty insurance and liability insurance in such form and in such amounts which are consistent with and comparable to the coverage of casualty insurance policies and liability insurance policies carried by landlord's owning commercial buildings located in Montgomery County, Maryland that are similar to the Leased Premises.

## (iv) Utility Expenses Not Separately Metered.

(aa) Throughout the Lease Term, Tenant agrees to pay to Landlord, as Additional Rent, Tenant's Proportionate Share of all water usage charges, exterior electric lighting charges, and any other utility charges ("Shared Charges") not separately metered (and only for so long as each is not separately metered) for each of the Leased Premises, the Adjacent Laboratory Building, and the common areas of the Property.

(bb) Upon receipt of each billing for Shared Charges, Landlord will as soon as practicable submit to Tenant a statement of Shared Charges incurred for the preceding billing period. Tenant shall pay Landlord, within thirty (30) days of Tenant's receipt of such statement, Tenant's Proportionate Share of Shared Charges.

(v) Landlord's Enforcement Costs. Additional Rent shall include any and all expenses incurred by Landlord, including reasonable attorneys' fees, for the collection of monies due from Tenant and the enforcement of Tenant's obligations under the provisions of this Lease. In the event Minimum Annual Rent or Additional Rent is not paid within fifteen (15) business days of its due date, Landlord, at its sole option, may assess a late charge equal to five percent (5%) of the amount of the delinquent Basic Monthly Rent and Additional Rent as compensation for the additional administrative costs incurred by Landlord as a result of such late payment.

(c) Payment of Rent. Any Minimum Annual Rent or Additional Rent which is not paid within five (5) business days after the same is due shall bear interest ("Penalty Rate") at one percentage (1%) point above the prime rate of interest by NationsBank/Maryland existing from time to time and adjusted each day the prime rate is redetermined to reflect the change in said prime rate of interest, from the due date until the date received by Landlord. Any payments of Minimum Annual Rent or Additional Rent by Tenant or acceptance by Landlord of a lesser amount than shall be due from Tenant to Landlord shall be treated as a payment on account. The acceptance by Landlord of a check for a lesser amount with an endorsement or statement thereon, or upon any letter accompanying such check, that such lesser amount is payment in full, shall be given no effect, and Landlord may accept such check without prejudice to any other rights or remedies which Landlord may have against Tenant. If Landlord receives from Tenant two (2) returned or "bounced" checks in any one Lease Year. Landlord may require all future Rent by cashier's or certified check.

#### 5. Security Deposit.

(a) Contemporaneously with the execution of this Lease, Tenant has deposited with Landlord the sum specified in Section 1(a)(10) as the security deposit ("Security Deposit"), the receipt of which is hereby acknowledged. Said Security Deposit shall serve as security for the faithful performance by Tenant of all the terms, covenants and conditions of this Lease to be kept and performed by Tenant during the Lease Term. If, at any time during the Lease Term, any payment of Minimum Annual Rent or Additional Rent herein reserved shall be overdue and unpaid, then Landlord may, at its option, appropriate and apply any portion of said Security Deposit to the payment of any such overdue rent or other sum.

(b) In the event of the failure of Tenant to keep and perform any of the terms, covenants and conditions of this Lease to be kept and performed by Tenant, then Landlord, at its option, may appropriate and apply the entire Security Deposit, or so much thereof as may be necessary, to compensate Landlord for loss or damage sustained or suffered by Landlord due to such breach on the part of Tenant. Should the entire Security Deposit, or any portion thereof, be appropriated and applied by Landlord for the payment of overdue rent or other sums due and payable to Landlord by Tenant hereunder, then Tenant shall, upon the written demand of Landlord, forthwith remit to Landlord a sufficient amount in cash to restore the Security Deposit to the original sum. Tenant's failure to do so within five (5) days after receipt of such demand shall constitute a breach of this Lease. Should Tenant comply with all of said terms, covenants and conditions of this Lease and promptly pay all Minimum Annual Rent and Additional Rent herein provided as it falls due, then the Security Deposit (and all accrued interest) shall be returned in full to Tenant within forty-five (45) days of the Expiration Date or earlier termination of the Lease Term.

(c) Landlord shall deliver the funds deposited hereunder by Tenant as a Security Deposit to the purchaser of Landlord's interest in the Property and/or the Leased Premises in the event that such interest is sold, and thereupon Landlord shall be discharged from any further liability with respect to such Security Deposit.

(d) If the Tenant fails to take possession of the Leased Premises as required by this Lease, the Security Deposit shall not be deemed liquidated damages, and Landlord's use of the Security Deposit pursuant to this Section 5 shall not preclude Landlord from recovering from Tenant all additional damages incurred by Landlord.

(e) Landlord shall deposit the funds delivered by Tenant as a Security Deposit in an interest bearing, federally insured account, and shall hold the Security Deposit in such an account(s) during the entire Lease Term. For so long as Signet Bank/Maryland holds a first lien security interest in the Property, the Security Deposit shall be held in an account at Signet Bank/Maryland which identifies Landlord as the escrow agent or custodian of the proceeds constituting the Security Deposit for the benefit of Tenant. All interest earned on said account shall be credited to Tenant, and, so long as Tenant is not in default of its obligations under this Lease, Landlord shall pay to Tenant all accrued interest (and shall deliver to Tenant an appropriate statement showing the accrual of such interest on said account) on or before the 31st day of January of each calendar year during the Lease Term. Tenant acknowledges that its tax identification number is #04-3152484 for purposes of reporting to the Internal Revenue Service interest earned on said account.

#### 6. Use.

- (a) Use. Tenant shall use the Leased Premises for the purposes specified in Section 1(a)(9), and for no other purpose.
- (b) Compliance With Laws, Fire Insurance, Condition of Leased Premises. Tenant shall not do, or permit anything to be done in the Leased Premises or on the Property, or bring or keep anything therein, which will in any way invalidate or conflict with fire insurance policies on the Property, including, but not limited to all improvements, the Property's fixtures and personal property kept therein, or obstruct or interfere with the rights of the Landlord or of other tenants of the Property, or in any other way injure or annoy Landlord or such other tenants, or subject Landlord to any liability for injury to persons or damage to property, or interfere with the good order of the Property, as determined by Landlord in its sole reasonable discretion. Tenant shall refrain or discontinue said use immediately upon receipt of written notice from Landlord requiring such action. Tenant, at its expense, shall comply with all present and future laws, rules or regulations of any federal, state or municipal authority, or the Maryland Fire Underwriters Rating Bureau, or with any notice from any public officer pursuant to law pertaining to Tenant's occupancy or use of the Leased Premises, whether such notice shall be served on Landlord or Tenant (including, where necessary, the construction of capital improvements to the Leased Premises). Tenant agrees to indemnify, defend, and hold Landlord harmless from all liability, damage, cost, and expense (including, without limitation, court costs and reasonable attorneys fees) resulting from any injury to persons or damage to property occurring in or around the Leased Premises, whether occasioned by any act or omission of Tenant, Tenant's agents, contractors, servants, employees, invitees or licensees. Tenant agrees that any increases of fire insurance premiums on the Leased Premises or contents caused by the occupancy of Tenant and any expenses or costs incurred in consequence of negligence or carelessness or the willful action of Tenant, Tenant's employees, agents, contractors, servants, invitees, or licensees shall be deemed Additional Rent and paid by Tenant to Landlord as they accrue.

## 7. Common Areas.

(a) Common Areas Defined. In this Lease, "common areas" means all areas, facilities and improvements provided, from time to time, on the Property for the mutual convenience and use of all tenants or other occupants of the Leased Premises and the Adjacent Laboratory Building, their respective agents, employees, and invitees, and shall include, if provided, but are not limited to, parking areas and facilities, access roads,

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driveways, retaining walls, sidewalks, walkways, landscaped areas, and exterior lighting facilities.

(b) Landlord's Control. Landlord shall, as between Landlord and Tenant, at all times during the Lease Term have the sole and exclusive control, management and direction of the common areas, and may, at any time and from time to time during the Lease Term, exclude and restrain any person from use or

occupancy thereof, excepting, however, Tenant and other tenants of Landlord and bona fide invitees of either who make use of said areas in accordance with the rules and regulations established by Landlord from time to time with respect thereto. The rights of Tenant in and to the common areas shall at all times be subject to the rights of others to use the same in common with Tenant, and it shall be the duty of Tenant to keep all of said areas free and clear of any obstructions created or permitted by Tenant or resulting from Tenant's operation. Landlord may at any time and from time to time (i) close all or any portion of the common areas to make repairs or changes, (ii) close all or any portion of the common areas to such extent as may, in the opinion of Landlord, be necessary to prevent a dedication thereof or the accrual of any rights to any person or to the public therein, and (iii) do and perform such other acts in and to said areas as, in the exercise of good business judgment, Landlord shall determine to be advisable with a view to the improvement of the convenience and use thereof by tenants, their employees, agents, and invitees. Landlord shall at all times have the right and privilege of determining the nature and extent of the common areas, and of making such changes, rearrangements, additions or reductions therein and thereto from time to time which in its opinion are deemed to be desirable and for the best interest of all persons using the common areas or which are as a result of any federal, state or local environmental protection or other law, rule, regulation, guideline or order. The purpose of the site plan attached hereto as Exhibit A is to show the approximate locational relationship of the Leased Premises to the Adjacent Laboratory Building and to the common areas as of the Rent Commencement Date. Nothing described in Exhibit A shall limit or prevent Landlord from effecting any change or alteration to the Property as described in this paragraph. Nothing contained in this Section shall give Landlord the right to impose restrictions on the use and enjoyment of the common areas by Tenant, or to make modifications to the common areas, in a way to cause Tenant to be unable to use the Leased Premises and the common areas in a reasonable manner for the purposes originally contemplated by this Lease.

- (c) Parking Spaces. During the Lease Term, Tenant shall have the exclusive right to the use of all parking spaces in the common areas of the Property, except for the six (6) parking spaces which are marked in red on Exhibit A and are reserved by Landlord for its use.
- 8. Rules and Regulations. Tenant agrees to comply with and observe any reasonable rules and regulations promulgated by Landlord as set forth in Exhibit C, which may be supplemented or amended from time to time by Landlord. Tenant's failure to keep and observe said rules and regulations shall constitute a breach of the terms of this Lease in the same manner as if the same were contained herein as covenants.
- 9. Utilities. Tenant shall be solely responsible for and shall promptly pay any and all utility charges including but not limited to electricity, fuel, gas, and telephone (including equipment and installation charges) used in, consumed at, or supplied to the Leased Premises. Tenant shall immediately transfer all separately metered utility accounts for the Leased Premises into its own name on the Rent Commencement Date. Tenant shall pay to Landlord, as Additional Rent, its Proportionate Share of any and all bills for utility charges which are not

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separately metered in the manner described in Section 4(b)(iv) hereof.

10. Landlord's Right of Entry. Landlord, and its agents, shall have the right, upon prior notice to Tenant and during reasonable business hours during the Lease Term (except in the case of an emergency involving damage to person or property), to enter upon the Leased Premises to examine the same, or to make such repairs, alterations or improvements, as Landlord may deem necessary or proper, or to remove any alteration or improvement which is in violation of the provisions of this Lease, provided, however, Landlord shall not adversely interfere with Tenant's business operations in a material manner. Landlord reserves the right to show the Leased Premises to prospective tenants or brokers during the last ninety (90) days of the Lease Term, and to show the Leased Premises to prospective purchasers at all reasonable times, provided that prior

verbal notice is given to Tenant in each case and that Tenant's use and occupancy of the Leased Premises shall not be materially inconvenienced by any such action of Landlord.

## 11. Condition - Maintenance and Repair.

(a) Tenant's Responsibility. Tenant shall maintain the Leased Premises in substantially the same good order and condition as it is on the commencement of the Lease Term and shall return the Leased Premises to Landlord in such condition at the Expiration Date or at the earlier termination of this Lease, ordinary wear and tear excepted. Except as obligations to repair are expressly delegated to Landlord as described in Section 11(b) below. Tenant shall be responsible for the full cost of all maintenance and repair of (i) the Leased Premises, including but not limited to the doors, door jambs, windows, window casings and sills, screens, floor coverings, walls (excluding load bearing structures), and ceilings located in the Leased Premises, and all pipes, gutters, downspouts, wires, conduits and other equipment and fixtures located in the Leased Premises, and (ii) the common areas of the Property (including all landscaping thereon, except for the landscaping immediately surrounding the Adjacent Laboratory Building). Tenant, at its expense, shall perform routine maintenance, repair, and replacement of the plumbing, electrical, heating, ventilating and air-conditioning systems, and all other systems and equipment, serving the Leased Premises. Tenant will throughout the Lease Term obtain and keep in force a maintenance contract with a qualified service company to regularly inspect and perform maintenance services to the heating, ventilating and air-conditioning system serving the Leased Premises. Tenant, at its expense, shall furnish Landlord with a copy of said maintenance contract, and of renewals or replacements thereof, promptly after the effective date thereof. All repairs and maintenance required to be performed by Tenant at the Leased Premises shall be made or performed within a reasonable period of time upon the occurrence of the necessity therefor, and shall be made or performed in a workmanlike manner, using first class materials, by a contractor duly licensed in the State of Maryland, and shall be made or performed in accordance with (i) all applicable federal, state and county governmental codes and regulations, and (ii) insurance requirements. Tenant shall also be responsible for keeping all sidewalks and parking areas on the Property free and clear of dirt, trash, debris, ice, snow, and any other obstructions; provided, however, that Landlord shall upon request promptly reimburse Tenant for nine percent (9%) of the cost of any such services. Tenant shall keep its trash and garbage in enclosed containers in a trash holding area within the Leased Premises, and shall perform regular trash removal from such trash holding area. Tenant shall also be responsible for the performance of regular, periodic pest control services at the Leased Premises. All glass, both exterior and interior, shall be maintained in the Leased Premises at the sole

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risk of Tenant, and Tenant agrees to replace any glass promptly at its sole expense in the event of breakage.

(b) Landlord's Responsibility. Except for any structural alterations or improvements made by Tenant, Landlord shall maintain in good order and repair the roof and the structural portions of the foundation, floors, stairwells, exterior walls, columns and other load bearing elements of the Leased Premises, and shall perform all non-routine repair and replacement of the heating, ventilating and air-conditioning system at the Leased Premises, provided, in each case, that Tenant shall give Landlord notice of the necessity therefor, whereupon Landlord shall have a reasonable period of time within which to make such repairs, and provided, further, that any such repairs necessitated by the acts or omissions of Tenant, its agents, employees, contractors or invitees, shall be performed at Tenant's expense, and the cost thereof shall be paid by Tenant to Landlord, as Additional Rent, within twenty (20) days after Landlord's submission of a bill therefor.

12. Alterations or Improvements by Tenant. Except for incidental painting and decoration of the interior of the Leased Premises and other minor

alterations and improvements which do not affect the structure or utility systems of the Leased Premises, Tenant shall not make any alterations, additions, or improvements, structural or otherwise (collectively, "Alterations") in, on or to the Leased Premises, without the prior written consent of Landlord, which consent shall not be unreasonably withheld or delayed. In connection with Landlord's review of such proposed alterations or improvements prior to giving its consent thereto, Landlord shall have the right to require that Tenant supply plans, specifications, working drawings and similar documents in reasonable detail which show the scope of work to be performed within the Leased Premises. Landlord's approval of the plans, specifications and working drawings for Tenant's alterations and improvements shall create no liability on the part of Landlord for their completeness, design sufficiency, or compliance with all laws, rules, regulations of governmental agencies or authorities. Landlord acknowledges that Tenant desires to build a P3 laboratory in the Leased Premises during the Lease Term, and that Landlord shall not unreasonably withhold or delay its consent to the construction thereof. Any contractors employed by Tenant to perform Tenant's work (i) shall be qualified to perform such work and licensed in the State of Maryland and (ii) shall maintain any insurance which may be reasonably required by Landlord, and (iii) shall be bonded or otherwise reasonably satisfactory to Landlord. Tenant will defend, indemnify and hold Landlord harmless from and against any and all expenses, liens, claims or damages, including attorneys' fees, for injury to person or property which may or might arise, directly or indirectly, by reason of the making of any Alterations. If any Alterations are effected without the prior written consent of Landlord, Landlord may remove or correct the same and Tenant shall be liable for any and all expenses of this work. All rights given to Landlord herein shall be in addition to any other right or remedy of Landlord contained in this Lease. Tenant shall be obligated to make any and all Alterations and other improvements to the Leased Premises required by applicable federal, state, and local law, in connection with the use of the Leased Premises by Tenant during the Leased Term. Tenant hereby agrees that all Alterations made in, to, or on the Leased Premises shall, unless otherwise provided by written agreement or by the provisions of Section 13 below, be the property of Landlord and shall remain upon and be surrendered with the Leased Premises on the Expiration Date or other termination of this Lease.

13. Surrender. Upon the Expiration Date or other termination of the Lease Term, Tenant shall quit and surrender the Leased Premises to the Landlord in good order and condition,

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ordinary wear and tear excepted, and Tenant shall remove all of its personal property from the Leased Premises on or before the Expiration Date or other termination of this Lease. Tenant's obligation to observe or perform the covenants described in this Section 13 shall survive the expiration or other termination of this Lease. If Tenant does not remove Tenant's furniture, trade fixtures and all other items of personal property of every kind and description from the Leased Premises as specified herein, then Landlord shall be permitted to remove, dispose or otherwise discard such property without further payment or credit by Landlord to Tenant. Notwithstanding anything to the contrary contained in this Lease, Tenant shall have the right and the obligation, at the end of the Lease Term, to remove all built-in desks, cabinets, basins, emergency showers and other pieces of equipment which are affixed to the Leased Premises by Tenant. In connection with the removal of said equipment, Tenant shall be obligated to stub pipes; bundle and cap wires; close ducts; repair and replace (as appropriate) flooring coverings; repair, replace, finish and repaint (as appropriate) walls, and perform all other acts which are necessary for the Leased Premises to be returned to Landlord in same good order and condition as exists of the Rent Commencement Date.

14. Tenant Holding Over. If Tenant holds possession of the Leased Premises after the Expiration Date or other termination of this Lease, Landlord shall have the option, exercisable in writing within thirty (30) days after the date of termination as aforesaid, to treat Tenant as a trespasser, or as a tenant by the month. If the Landlord fails to make such election then the Tenant shall be deemed a tenant by the month, commencing with the first day after the

termination of the Lease at one hundred fifty percent (150%) of the Basic Monthly Rent paid during the last month of the Lease Term, and upon all the other terms of this Lease, including the provisions of this Section. Said holdover term shall terminate upon thirty (30) days notice from one party to the other. Nothing contained herein shall be construed within said thirty (30) days after the date of Lease termination as aforesaid as a consent by Landlord to the occupancy or possession of the Leased Premises by Tenant after the termination of the Lease, and Landlord, upon said termination, if Landlord elects to treat Tenant as a trespasser, shall be entitled to the benefit of all general or public laws relating to the speedy recovery of the possession of land and tenements held over by Tenant, whether now or hereafter in force and effect. If Tenant fails to surrender the Leased Premises upon the expiration or other termination of this Lease despite demand to do so by Landlord, Tenant shall indemnify, defend, and hold Landlord harmless from all injury, loss, claims, expenses and liability, including without limitation, any claim made by any succeeding tenant and any attorneys' fees, founded on or resulting from such failure to surrender.

## 15. Assignment and Subletting.

(a) Assignment by Tenant. Tenant shall not assign, mortgage or encumber this Lease, or any right hereunder, nor sublet the Leased Premises or any part thereof, nor permit the Leased Premises to be used by others without the prior written consent of Landlord, which consent shall be at Landlord's sole discretion. If Tenant is a corporation, unincorporated association or partnership, then the transfer, assignment or hypothecation of any stock or interest in such corporation, association or partnership so as to result in a change of fifty percent (50%) or more in the ownership thereof by the person, persons or entities owning said entity as of the date of this Lease, without the prior written consent of Landlord (which consent shall not be unreasonably withheld or delayed), shall be deemed an assignment made in breach of this covenant. Landlord's consent in any specific instance to any assignment, mortgage, encumbrance, subletting or use of the Leased Premises and its

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collection and acceptance of rent from any such approved assignee, subtenant or other occupant shall neither constitute a waiver of the provisions of this paragraph, nor be construed as permission of any subsequent assignment, mortgage, encumbrance, subletting or use without compliance with this paragraph. Without the prior written consent of Landlord, this Lease and the interest of Tenant, or any assignee of Tenant, shall not pass by operation of law, nor shall it be subject to garnishment or sale under execution in any suit or proceeding which may be brought against or by Tenant, or any assignee of Tenant. No assignment of this Lease, sublease of all or any portion of the Leased Premises, or collection of rent from an assignee or subtenant (whether or not permitted by Landlord) shall relieve Tenant of its obligations hereunder. In the event that Landlord gives Tenant its written consent to assign, transfer, or sublet all or a portion of the Leased Premises to a third party which is unrelated to Tenant, any monthly rent or other payment accruing to Tenant as the result of any such assignment, transfer or sublease, including any lump sum or periodic payment in any manner relating to such assignment, transfer or sublease, which is in excess of the Minimum Annual Rent and Additional Rent then payable by Tenant under the Lease shall be paid by Tenant to Landlord monthly as Additional Rent, excluding any reasonable expenses incurred by Tenant in connection with such assignment or subletting, e.g. legal fees and brokers' commissions. Landlord may require a certificate from Tenant specifying the full amount of any such payment of whatsoever nature. Any reasonable costs and expenses, including reasonable attorneys' fees incurred by Landlord in connection with any proposed or purported assignment, transfer or sublease shall be borne by Tenant and shall be payable to Landlord as Additional Rent within five (5) days of demand therefor.

Notwithstanding anything herein to the contrary, Tenant shall have the right, without Landlord's prior written consent, to assign this Lease or sublet the Leased Premises to any parent corporation of Tenant, or to any subsidiary of any parent corporation of Tenant, subject to the following express

conditions:

- (i) No such assignment or sublease shall be deemed to release Tenant from continuing liability for all of Tenant's covenants and obligations under this Lease, or Boston Biomedica, Inc. ("Tenant's Guarantor") from its obligations under its Guaranty; and
- (ii) Any assignee or subtenant must expressly assume in writing all of the covenants and obligations of Tenant under this Lease, joint and severally with Tenant.

Further, Landlord agrees not to unreasonably withhold its consent to an assignment of this Lease (or to a sale or transfer of Tenant's stock) resulting from a merger, consolidation, corporate reorganization (other than pursuant to the bankruptcy laws), sale of the assets or other transfer of stock of Tenant, subject to the following conditions:

- (i) Such assignee or transferee, as the case may be, shall have a net worth at least equal to that of Tenant, as of the date hereof, or the date of such request for consent to an assignment or transfer, whichever is greater;
- (ii) No such assignment shall be deemed to release Tenant's Guarantor from its obligations under its Guaranty; and
- (iii)Such assignee or transferee, as the case may be, must expressly assume in writing all of the

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covenants and obligations of Tenant under this Lease, jointly and severally with Tenant.

Further, any issuance by Tenant of its capital stock in a public offering which is effected in compliance with the registration requirements of the Securities Act of 1933, as amended, and the rules and regulations thereunder, shall not be deemed to be a change in control or an assignment of this Lease requiring Landlord's consent.

(b) Assignment by Landlord. It is expressly understood and agreed that this Lease and all rights of Landlord hereunder shall be fully and freely assignable by Landlord without notice to, or consent of, Tenant. In the event of the transfer and assignment by Landlord of its interest in this Lease, Landlord shall thereby be released from any responsibility for the performance of obligations thereafter accruing hereunder, and Tenant agrees to look solely to such successor in interest of the Landlord for performance of such obligations. Nothing contained herein shall prevent Tenant from looking to Landlord for the performance of obligations of which Landlord has actual knowledge and which predate the effective date of the transfer and assignment by Landlord of its interest in this Lease. The term "Landlord" as used in this Lease shall mean the owner of the Leased Premises, at the time in question. In the event of a transfer (whether voluntary or involuntary) by such owner of its interest in the Leased Premises, such owner shall thereupon be released and discharged from all covenants and obligations of the Lease thereafter accruing, but such covenants and obligations shall be binding during the Lease Term upon each new owner for the duration of such owner's ownership.

## 16. Bankruptcy.

(a) The following shall be Events of Bankruptcy under this Lease: (1) Tenant or any guarantor of Tenant's obligations under this Lease ("Tenant's Guarantor") becoming insolvent, as that term is defined in Title 11 of the United States Code (the "Bankruptcy Code"), or under the insolvency laws of any state, district, commonwealth or territory of the United States (the

"Insolvency Laws"); (2) the appointment of a receiver or custodian for any or all of Tenant's or Tenant's Guarantor's property or assets, or the institution of a foreclosure action upon any of Tenant's or Tenant's Guarantor's real or personal property; (3) the filing of a voluntary petition under the provisions of the Bankruptcy Code or Insolvency Laws by Tenant or Tenant's Guarantor; (4) the filing of an involuntary petition against Tenant or Tenant's Guarantor as the subject debtor under the Bankruptcy Code or Insolvency Laws, which either (A) is not dismissed within one hundred twenty (120) days of the date of filing, or (B) results in the issuance of an order for relief against the debtor; or (5) Tenant's or Tenant's Guarantor's making or consenting to an assignment for the benefit of creditors or a common law composition of creditors.

(b) Upon occurrence of an Event of Bankruptcy, Landlord shall have all rights and remedies available to Landlord pursuant to Section 18; provided, however, that while a case in which Tenant is the subject debtor under the Bankruptcy Code is pending, Landlord shall not exercise its rights and remedies pursuant to Section 20 so long as (1) the Bankruptcy Code prohibits the exercise of such rights and remedies, and (2) Tenant or its Trustee in Bankruptcy (hereinafter referred to as "Trustee") (i) cures all defaults under this Lease, (ii) compensates Landlord for monetary damages incurred as a result of such defaults, (iii) provides adequate assurance of future performance on the part of Tenant as debtor in possession or on the part of the assignee tenant, and (iv) complies with all other requirements of the Bankruptcy Code and this Lease.

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- 17. Default. Each of the following shall be deemed a default by Tenant and a material breach of this Lease:
  - (a) An Event of Bankruptcy as defined in Section 16;
  - (b) An assignment or encumbrance of Tenant's interest in this Lease or the Leased Premises or a subletting of any part of the Leased Premises in violation of Section 15;
  - (c) A failure by Tenant to make any payment of Minimum Annual Rent or Additional Rent within five (5) days of receipt of written notice that such payment was not received on its due date (provided that Landlord shall not be obligated to provide Tenant with such written notice more than twice during any twelve month period during the Lease Term, and after receipt of such second notice, Tenant shall be deemed in default, without further notice, if any such payment is not received by Landlord on its due date);
  - (d) Abandonment of the Leased Premises; and
  - (e) A failure by Tenant in the performance of any other term, covenant, agreement or condition of this Lease on the part of Tenant to be performed after fifteen (15) days notice, or if such default cannot reasonably be cured within said fifteen (15) day period and Tenant does not commence to diligently pursue the same within said fifteen (15) day period and to continue to diligently pursue the same until remedied.

Landlord agrees that it shall not exercise any rights or remedies, which are available to it pursuant to the terms of Section 18, as a result of an event of default described in Section 17 (b) or (d) above, unless and until Landlord has provided Tenant with a period of fifteen (15) days after receipt of written notice thereof within which to cure such default.

18. Landlord's Rights Upon Tenant's Default. Upon default by Tenant of any of the terms or covenants of this Lease, Landlord shall be entitled to

- (a) Landlord shall have the right, immediately or at any time after said default, without further notice to Tenant (unless otherwise provided herein), to enter the Leased Premises, without terminating this Lease or being guilty of trespass, and do any and all acts as Landlord may deem necessary, proper or convenient to cure such default, for the account and at the expense of Tenant, and Tenant agrees to pay to Landlord as Additional Rent all damage and/or expense incurred by Landlord in so doing, including interest at the Penalty Rate from the due date until the date payment is received by Landlord. The making of such payment or the taking of such action by Landlord shall not be deemed to cure the default or to stop Landlord from the pursuit of any remedy to which Landlord would otherwise be entitled.
- (b) Landlord shall, following said default, have the right to terminate this Lease and/or Tenant's right to possession of the Leased Premises and, with or without legal process, take possession of the Leased Premises and remove Tenant, any occupant and any property therefrom, without being guilty of trespass and without relinquishing any rights of Landlord against Tenant. Landlord shall be entitled to

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damages from Tenant in an amount equal to the amount herein covenanted to be paid as Minimum Annual Rent during the remainder of the Lease Term, said Minimum Annual Rent for the full term then remaining having been fully accelerated at the option of Landlord, together with (i) all reasonable expenses of any proceedings (including, but not limited to, legal expenses and attorney's fees) which may be necessary in order for Landlord to recover possession of the Leased Premises, (ii) the reasonable expenses of the re-renting of the Leased Premises (including, but not limited to, any commissions paid to any real estate agent, advertising expense and the costs of such alterations, repairs, replacements and decoration or re-decoration as Landlord, in its sole judgment reasonably exercised, considers advisable and necessary for the purpose of re-renting the Leased Premises), and (iii) interest computed at the Penalty Rate from the due date until paid; provided, however, that said damages shall be discounted to present value using a discount factor of 5%, and further that there shall be credited against the amount of such damages all amounts received by Landlord from such re-renting of the Leased Premises and such amounts shall be refunded to Tenant. No act or thing done by Landlord shall be deemed to be an acceptance of a surrender of the Leased Premises, unless Landlord shall execute a written agreement of surrender with Tenant. Tenant's liability hereunder shall not be terminated by the execution of a new lease of the Leased Premises by Landlord. In the event Landlord does not exercise its option to accelerate the payment of Minimum Annual Rent as provided hereinabove, then Tenant agrees to pay to Landlord, upon demand, the amount of damages herein provided after the amount of such damages for any month shall have been ascertained; provided, however, that any expenses incurred by Landlord shall be deemed to be a part of the damages for the month in which they were incurred. Separate actions may be maintained each month or at other times by Landlord against Tenant to recover the damages then due, without waiting until the end of the term of this Lease to determine the aggregate amount of such damages.

(c) Upon any default by Tenant to pay Minimum Annual Rent or Additional Rent, Landlord shall have a lien upon the property of Tenant in the Leased Premises for the amount of any unpaid Minimum Annual Rent or Additional Rent. In such event, Tenant shall not remove any of Tenant's property from the Leased Premises except with the prior written consent of Landlord, which consent shall be granted at Landlord's sole and absolute discretion.

herein as a result of a default by the other party shall be cumulative, and none shall exclude any other right or remedy allowed by law. For the purposes of any suit brought or based hereon, this Lease shall be construed to be a divisible contract, to the end that successive actions may be maintained on this Lease as successive periodic sums mature hereunder.

### 19. Lender Requirements.

(a) Subordination. Tenant agrees that this Lease is subject and subordinate to the lien of any existing mortgage or deed of trust which is a lien upon the Property or any part thereof on the Rent Commencement Date, and to all renewals, modifications, consolidations, replacements and extensions thereof, and to all advances made or hereafter to be made upon the security thereof. Landlord agrees that it shall use reasonable efforts to acquire from any such existing mortgagee or holder of an existing deed of trust a non-disturbance agreement in such lender's usual form for the benefit of Tenant. Tenant agrees that this Lease is and shall be subject and subordinate to the lien of any future mortgages or deeds of trust which at any time during the Lease Term may be made a lien upon the Property or any part thereof, and to all advances made or hereafter to be

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made upon the security thereof; provided that such subordination shall be effective only upon the delivery to Tenant of a non-disturbance agreement in such lender's usual form for the benefit of Tenant by such future mortgagee or holder of a deed of trust. These subordination provisions shall be self-operative and no further instrument of subordination shall be required. Tenant agrees to execute and deliver, upon request, such further instrument or instruments confirming this subordination as shall be desired by Landlord or by any mortgagee or proposed mortgagee; and Tenant hereby constitutes and appoints Landlord as Tenant's attorney-in-fact to execute any such instrument or instruments. Tenant further agrees that, at the option of the holder of any mortgage or of the trustee under any deed of trust, this Lease may be made superior to said mortgage or deed of trust by the insertion therein of a declaration that this Lease is superior thereto, and to all renewals, modifications, consolidations, replacements and extensions thereof.

- (b) Attornment. In the event any proceedings are brought for the foreclosure of, or in the event of exercise of the power of sale under, any deed to secure a debt given by Landlord and covering the Leased Premises, Tenant shall execute such attornment agreement as shall be reasonably required by said purchaser, pursuant to the terms of which Tenant recognizes such purchaser as the owner and landlord under this Lease, and the purchaser recognizes Tenant as the tenant under this Lease.
- (c) Notice to Mortgagee Upon Landlord Default. Tenant agrees to give any mortgagee by certified mail, return receipt requested, a copy of any notice of default served upon Landlord, provided that before such notice Tenant has been notified in writing of the address of such mortgagee. Tenant further agrees that if Landlord shall have failed to cure such default within the time provided for in this Lease, then mortgagee shall have an additional fifteen (15) days within which to cure such default; provided, however, that if such default cannot be reasonably cured within that time, then such mortgagee shall have such additional time as may be necessary to cure such default so long as mortgagee has commenced and is diligently pursuing the remedies necessary to cure such default (including, without limitation, the commencement of foreclosure proceedings, if necessary), in which event this Lease shall not be terminated while such remedies are being so diligently pursued. In the event of the sale of the Property or the Leased Premises, by foreclosure or deed in lieu thereof, the mortgagee or purchaser at such sale shall be responsible for the return of the security deposit only to the extent that such mortgagee or purchaser actually received the security deposit. In addition, Tenant shall not pay any rental hereunder for more than one (1) month in advance.

time, upon not less than five (5) business days prior notice by Landlord, to execute, acknowledge and deliver to Landlord a statement in writing (i) certifying that this Lease is unmodified and in full force and effect (or if there have been modifications the nature of same), (ii) stating the dates to which the Minimum Annual Rent and Additional Rent have been paid by Tenant, (iii) stating whether or not to the best knowledge of Tenant, Landlord is in default in the performance of any covenant, agreement or condition contained in this Lease, and, if so, specifying each such default of which Tenant may have knowledge, (iv) stating the address to which notices to Tenant should be sent, and (v) certifying such other matters as may be requested by Landlord. Any such statement delivered pursuant hereto may be relied upon by an owner of the Property, any prospective purchaser of the Property, any mortgagee or prospective mortgagee of the Property, or of Landlord's interest therein, or any prospective assignee of any such mortgage.

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## 21. Damage by Fire or Other Casualty.

- (a) Restoration. If the Leased Premises shall be damaged by fire or other casualty but such damage does not render the Leased Premises wholly unfit for Tenant's business operations as shall be determined by Landlord and Tenant in their reasonable business judgment, Landlord, at Landlord's expense, shall promptly restore the Leased Premises, and Tenant, at Tenant's sole expense, shall promptly restore all leasehold improvements installed in the Leased Premises by Tenant or at Tenant's request and its own furniture, furnishings, trade fixtures and equipment. No penalty shall accrue for reasonable delay which may arise by reason of adjustment of insurance on the part of Landlord, or on account of labor problems, or any other cause beyond Landlord's reasonable control. Minimum Annual Rent and Additional Rent shall abate proportionately (based on the proportion of the number of square feet rendered untenantable to the total number of square feet of the Leased Premises), from the date of the damage or destruction until the date the Landlord has substantially completed such restoration. Notwithstanding anything stated to the contrary herein, in the event that such damage shall occur during the last year of the Lease Term, Landlord shall not be required to restore the Leased Premises.
- (b) Termination. If the Leased Premises are substantially damaged or are rendered substantially untenantable by fire or other casualty during the Lease Term to such an extent that it is rendered substantially unusable by Tenant for the purposes originally contemplated by this Lease, Landlord shall restore or repair the same unless expressly not required to do so under Section 21(c). If such damage occurs, however, at any time during the Lease Term, and (i) Landlord's architect certifies that the Leased Premises cannot be repaired within one hundred twenty (120) working days of normal working hours, said period commencing on the casualty date, or (ii) Landlord shall decide to demolish the Leased Premises or not to rebuild it, then Landlord may, within ninety (90) days after such fire or other casualty, terminate this Lease by giving Tenant notice of such decision, and thereupon the Lease Term shall expire by lapse of time upon the third day after such notice is given, and Tenant shall thereupon vacate the Leased Premises and surrender the same to Landlord. In the event that damage to the Leased Premises cannot be repaired sufficiently within one hundred twenty (120) days after such fire or other casualty so that Tenant can commence to refixture the Leased Premises for the use thereof as originally contemplated by this Lease, then Tenant shall have the right to terminate this Lease by giving Landlord written notice thereof within said one hundred twenty (120) day period, and thereupon the Lease Term shall expire by lapse of time upon the third day after such notice is given, and Tenant shall thereupon vacate the Leased Premises and surrender the same to Landlord. Upon the termination of this Lease under the conditions hereinbefore provided, Tenant's liability for Minimum Annual Rent and Additional Rent shall cease as of the day following the casualty.
- (c) Lender's Approval. Notwithstanding anything to the contrary in this Section or in any other provision of this Lease, any obligation (under this Lease or otherwise) of Landlord to restore all or any portion of the Leased

Premises shall be subject to Landlord's receipt of approval of the same by the mortgagee(s) of Landlord (and any other approvals required by applicable laws), as well as receipt from any such mortgagee(s) of such fire and other hazard insurance policy proceeds as may have been assigned to any such mortgagee; it being agreed that if Landlord has not received such approval(s) and proceeds within one hundred and eighty (180) days after any such casualty, then Landlord shall have the option to terminate this Lease, at any time thereafter, by notice to Tenant. Landlord shall diligently

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pursue the receipt of all approvals and insurance policy proceeds which are described in this Section 21(c).

22. Condemnation. In the event the whole or a "substantial part" (as hereinafter defined) of the Leased Premises shall be taken for any public or quasi-public purpose by any lawful power or authority by exercise of the right of appropriation, condemnation or eminent domain, or sold to said authority to prevent such taking (collectively referred to herein as a "taking"), this Lease shall terminate effective as of the date possession is required to be surrendered to said authority, and the Minimum Annual Rent and Additional Rent shall be apportioned as of the date. For purposes of this Section, a "substantial part" of the Leased Premises shall be considered to have been taken if fifty percent (50%) or more of the Leased Premises is taken or condemned. Tenant shall not assert any claim against Landlord or the taking authority for any compensation arising out of or related to such taking and Landlord shall be entitled to receive the entire amount of any award without deduction for any estate or interest of Tenant; provided, however, that nothing contained in this section shall be deemed to give Landlord any interest in any award made to Tenant for the taking of personal property and fixtures belonging to Tenant or for Tenant's moving expenses, as long as such award is made in addition to and separately stated from any award made to Landlord for the Leased Premises and the Property. If less than fifty percent (50%) of the Leased Premises is so taken, the Lease shall continue to be in full force and effect, and the Minimum Annual Rent and Additional Rent shall be adjusted (based on the ratio that the number of square feet of rentable area taken from the Leased Premises bears to the number of rentable square feet in the Leased Premises immediately prior to such taking) as of the date possession is required to be surrendered to said authority; provided, however, Landlord shall have the right to determine that the Leased Premises should be demolished and not rebuilt, in which event Landlord may, within ninety (90) days after such taking, terminate this Lease by giving Tenant notice of such decision, and thereupon the Lease Term shall expire by lapse of time upon the third day after such notice is given, and Tenant shall thereupon vacate the Leased Premises and surrender the same to Landlord. In the event that the Lease remains in full force and effect in accordance with the terms described above, Landlord shall be obligated to repair and restore the Leased Premises to usable condition by Tenant, and such repair shall be a condition precedent to the continued effectiveness of this Lease. Landlord shall have no obligation to contest any taking.

23. Landlord's Liability. Landlord, or its agents, shall not be liable for any injury or damage to persons or property resulting from fire, explosion, falling plaster, steam, gas, electricity, water, rain, or leaks from any part of the Leased Premises, or from the pipes, conduits, appliances or plumbing works, or by dampness or by any other cause of whatsoever nature, unless caused by or due to the gross negligence of Landlord, its agents, servants, or employees. All personal property and equipment located in the Leased Premises shall be at the risk of Tenant.

24. Tenant's and Landlord's Liability. Tenant shall reimburse Landlord for all expense, damages or fines, incurred or suffered by Landlord by reason of any breach, violation or nonperformance by Tenant, or its agents, servants, or employees, of any covenant or provision of this Lease or the Rules and Regulations promulgated by Landlord hereunder from time to time, or by reason of damage to persons or property caused by moving property of or for Tenant in or out of the Property, or by the installation or removal of furniture or other property of or for Tenant, by reason of or arising out of the carelessness, negligence or improper conduct of Tenant, or its agents, servants, employees,

occupancy of the Leased Premises or the common areas of the Property. Landlord shall reimburse Tenant for all expense, damages or fines, incurred or suffered by Tenant by reason of any breach, violation or nonperformance by Landlord, or its agents, servants, or employees, of any covenant or provision of this Lease, by reason of or arising out of the gross negligence of Landlord, or its agents, servants, employees, invitees or licensees.

## 25. Indemnity.

- (a) By Tenant. Tenant shall indemnify and defend Landlord and its agents and employees and save them harmless from and against any and all claims, actions, damages, liabilities and expense in connection with loss of life, personal injury and/or damage to property arising from or out of any occurrence in, upon or at the Leased Premises, or the occupancy or use by Tenant of the Leased Premises or any part thereof, or occasioned wholly or in part by any act or omission of the Tenant, its agents, contractors, employees, servants, invitees or licensees, whether inside the Leased Premises or elsewhere in the Property.
- (b) By Landlord. Landlord shall indemnify and defend Tenant and its agents and employees and save them harmless from and against any and all claims, actions, damages, liabilities and expense in connection with loss of life, personal injury and/or damage to property occasioned wholly or in part by any act or omission of the Landlord, its agents, contractors, employees, servants, invitees or licensees, whether inside the Leased Premises or elsewhere in the Property.

## 26. Tenant's Insurance.

- (a) Coverages. Tenant shall have issued, pay the premiums therefor, and maintain in full force and effect during the Lease Term and any option period:
  - (i) Comprehensive Liability. commercial general liability insurance policy or policies in which the Landlord and Landlord's mortgagee(s) (and such additional persons and/or entities as Landlord may request) and Tenant shall be the insured, protecting the Landlord and Landlord's mortgagee(s) (and such additional persons and/or entities as Landlord may request) and Tenant in the amount of at least Three Million and No/100 Dollars (\$3,000,000.00) combined, single limit coverage for bodily injury, including death, or property damage, which amount may be increased from time to time by Landlord in its reasonable determination:
  - (ii) All-Risk Casualty. All-risk casualty insurance, naming Landlord (and such additional persons and/or entities as Landlord may request) and Tenant as insureds (as their interests may appear), written at replacement cost value and with replacement cost endorsement, covering all leasehold improvements installed in the Leased

Premises by Tenant or at Tenant's request and all of Tenant's personal property in the Leased Premises (including, without limitation, inventory, trade fixtures, floor coverings, furniture and other property removable by Tenant under the provisions of this Lease).

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- (iii) Workers' Compensation. If and to the extent required by law, workers' compensation and employer's liability or similar insurance in form and amounts required by law.
- (b) Policy Requirements. Tenant's failure to provide such insurance or failure to pay the premiums when due, shall be deemed a default hereunder. Any monies expended by Landlord to cure said default shall be deemed Additional Rent and shall be due and owing with Tenant's next payment of Basic Monthly Rent. All such policies shall contain only such reasonable deductible amounts as may be approved in advance by Landlord and shall contain a provision that Landlord shall receive not less than thirty (30) days advance notice in writing from the insurance company of any intention of the insurance company to cancel such policy or policies. Tenant shall provide written evidence to Landlord of its acquisition of such policies prior to the commencement of this Lease and prior to any renewal date of such policies. All policies shall be carried with a reputable insurance company qualified to do business in the State of Maryland and rated not lower than A-XII in the A.M. Best Rating Guide.
- (c) No Limitation of Liability. Neither the issuance of any insurance policy required under this Lease nor the minimum limits specified herein shall be deemed to limit or restrict in any way Tenant's liability arising under or out of this Lease.
- 27. Waiver of Subrogation. Landlord and Tenant mutually covenant and agree that each party, in connection with insurance policies required to be furnished in accordance with the terms and conditions of this Lease, or in connection with insurance policies which they obtain insuring such insurable interest as Landlord or Tenant may have in its own properties, whether personal or real, shall expressly waive any right of subrogation on the part of the insurer against the Landlord (and any mortgagee requested by Landlord) or Tenant as the same may be applicable, which right to the extent not prohibited or violative of any such policy is hereby expressly waived, and Landlord and Tenant each mutually waive all right of recovery against each other, their agents, or employees for any loss, damage or injury of any nature whatsoever to property or person for which either party carries insurance or is required by this Lease to carry insurance.
- 28. No Liens Permitted; Discharged. Tenant will not permit to be created or to remain undischarged any lien, encumbrance or charge (arising out of any work done or materials or supplies furnished, or claimed to have been done or furnished, by any contractor, mechanic, laborer or materialman or any mortgage, conditional sale, security agreement or chattel mortgage, or otherwise by or for Tenant) which might be or become a lien or encumbrance or charge upon the Property or any part thereof or the income therefrom. If any lien, or notice of lien on account of an alleged debt of Tenant or any notice of contract by a party engaged by Tenant or Tenant's contractor to work on the Leased Premises shall be filed against the Property or any part thereof, Tenant, within fifteen (15) days after notice of the filing thereof, will cause the same to be discharged of record by payment, deposit, bond, order of a court of competent jurisdiction or otherwise. If Tenant shall fail to cause such lien or notice of lien to be discharged within the period aforesaid, then, in addition to any other right or remedy, Landlord may, but shall not be obligated to, discharge the same either by paying the amounts claimed to be due or by procuring the

discharge of such lien by deposit or by bonding proceedings and in any such event Landlord shall be entitled, if Landlord so elects, to compel the prosecution of an action for the

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foreclosure of such lien by the lienor and to pay the amount of the judgment in favor of the lienor with interest, costs and allowances. Any amount so paid by Landlord and all reasonable costs and expenses, including attorneys' fees, incurred by Landlord in connection therewith, shall constitute Additional Rent payable by Tenant under this Lease and shall be paid by Tenant to Landlord on demand. Nothing herein contained shall obligate Tenant to pay or discharge any lien created by Landlord.

29. Signs, Awnings and Canopies. Tenant will not place or suffer to be placed or maintained on the exterior of the Leased Premises any sign, awning or canopy, or other written matter of any kind, without first obtaining Landlord's written approval which shall not be unreasonably withheld or delayed, provided that any such sign, awning, canopy or written matter is in compliance with the applicable federal, state and/or county regulations. Tenant further agrees to maintain in good condition and repair at all times such sign, awning, canopy, decoration, lettering, or written matter as may be approved. Any of said items so installed without such written approval and consent may be removed by Landlord at Tenant's expense.

30. Environmental Protection. Tenant and Tenant's employees and agents shall not dispose of any oil, petroleum or chemical liquids or solids, liquid or gaseous products or any hazardous waste or hazardous substance including, without limitation, asbestos (hereinafter collectively referred to as "hazardous waste"), as those terms are used in the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, or in any other federal, state or local law governing hazardous substances, as such laws may be amended from time to time (hereinafter collectively referred to as the "Act"), at, upon, under or within the Leased Premises or the Property, or into the plumbing or sewer or water system servicing the Leased Premises and/or the Property, nor shall Tenant, its agents or employees cause or permit the discharge, spillage, uncontrolled loss, seepage or filtration of any hazardous waste at, upon, under or within the Leased Premises or the Property or into the plumbing or sewer or water system servicing the same. Notwithstanding the foregoing, Landlord acknowledges that the use which Tenant contemplates for the Leased Premises involves the use, storage, and disposal of materials which are defined herein as hazardous waste, and Tenant shall have the right to maintain such materials on the Leased Premises so long as they are used, stored and disposed of in accordance with the Act. Tenant shall comply in all respects with the requirements of the Act and related regulations, and shall notify Landlord immediately in the event of its discovery of any hazardous waste at, upon, under or within the Leased Premises or the Property which has not been used, stored or disposed of in accordance with the Act. Tenant shall advise Landlord, in writing, of the identities of hazardous wastes being used and stored in the Leased Premises promptly upon written request from Landlord, but in no event less frequently than once every twelve (12) months. Tenant shall indemnify Landlord against all costs, expenses, liabilities, losses, damages, injunctions, suits, fines, penalties, claims, and demands, including reasonable attorneys' fees, arising out of any violation of or default by Tenant, and its employees and agents, in the covenants of this Section. The provisions of this Section shall survive the expiration of the Lease Term.

- 31. Notices. All notices to be given under this Lease shall be in writing and either (i) hand-delivered, (ii) sent by Federal Express (or other nationally recognized, overnight mail courier service), (iii) or mailed by United States Certified or Registered Mail, return receipt requested, postage prepaid. Notices should be delivered as follows:
  - (a) To Landlord to the attention of the "General Manager" at the business and mailing address

stated on page 1 of this Lease, with a copy to Shulman, Rogers, Gandal, Pordy & Ecker, P.A., 11921 Rockville Pike, Suite 300, Rockville, Maryland 20852, attn: Karl L. Ecker, Esquire. Pursuant to the terms of Section 19(a) hereof, for so long as Signet Bank/Maryland holds a first lien security interest in the Property, a copy of any notice of default served on Landlord shall be delivered to Signet Bank/Maryland at 7700 Wisconsin Avenue, Suite 400, Bethesda, Maryland 20814, attn: Ms. Susan Benninghoff, Vice President.

(b) To Tenant to the attention of Richard T. Schumacher, President, at the business and mailing address stated on page 1 of this Lease, with a copy to Brown Rudnick Freed & Gesmer, One Financial Center, Boston, Massachusetts 02111, attn: Howard L. Levin, Esquire.

Any such notice shall be deemed to be received on the date it is hand-delivered or delivered by Federal Express (or other nationally recognized, overnight mail courier service), or on the third day after the date on which it is deposited in the U.S. mails. Landlord, Tenant and Signet Bank/Maryland shall each have the right to change the person and/or address to which notices shall be delivered upon notice thereof to the other parties sent pursuant to the provisions of this paragraph.

- 32. Time. Landlord and Tenant acknowledge that time is of the essence in the performance of any and all obligations, terms, and provisions of this Lease.
- 33. Postponement of Performance. In the event that either party hereto shall be delayed or hindered in or prevented from the performance of any act required hereunder by reason of strikes, labor troubles, inability to procure labor or materials, failure of power, restrictive governmental laws or regulations, riots, insurrection, war, acts of God, fire or other casualty or other reason of a similar or dissimilar nature beyond the reasonable control of the party delayed in performing work or doing acts required under the terms of this Lease, then performance of such act shall be excused for the period of the delay and the period for the performance of any such act shall be extended for a period equivalent to the period of such delay; provided, however that nothing in this section shall excuse any delay in the payment of Minimum Annual Rent or Additional Rent; and provided, further, that delays or failures to perform resulting from lack of funds shall not be deemed delays beyond the reasonable control of a party. Nothing contained herein shall be construed to limit the provisions concerning the abatement of Minimum Annual Rent and Additional Rent resulting from fire and casualty damage or from condemnation damage to the Leased Premises as more fully described in Sections 21 and 22 hereof.
- 34. Brokers. Landlord and Tenant represent and warrant each to the other that neither has authorized any broker, agent or finder purporting to act on either's behalf in respect to this Lease transaction except the Leasing Broker specified in Section 1(a)(11), and each hereby agree to indemnify and hold harmless one from the other from and against any cost, expense, claims, liability or damage resulting from a breach of the representation and warranty herein contained.
- 35. No Waiver. No waiver by Landlord or Tenant of any breach of any of the terms, covenants, agreements, or conditions of this Lease shall be deemed to constitute a waiver of any succeeding breach thereof, or a waiver of any breach of any of the other terms, covenants, agreements, and conditions herein

contained. No provision of this Lease shall be deemed to have been waived by Landlord or Tenant, unless such waiver be in writing signed by such party. No employee of Landlord or of Landlord's agents shall have any authority to accept the keys of the Leased Premises prior to termination of the Lease, and the delivery of keys to any employee of Landlord or Landlord's agents shall not operate as a termination of the Lease or a surrender of the Leased Premises. The receipt by Landlord of any payment of Minimum Annual Rent or Additional Rent with knowledge of the breach of any covenant of this Lease shall not be deemed a waiver of such breach. The failure of Landlord to enforce any of the Rules and Regulations made a part of this Lease, or hereafter adopted, against Tenant or any other tenant in the Property shall not be deemed a waiver of any such Rules and Regulations.

- 36. Amendments. This Lease and the Exhibits attached hereto, together with the terms and conditions of that certain Assets for Cash Purchase Agreement, of even date, entered into by and between Landlord, Tenant and Tenant's Guarantor, which describe the sale and purchase of certain assets by Landlord to Tenant and Tenant's Guarantor, contain the entire agreement between the parties, and any agreement hereafter made shall be ineffective to change, modify, discharge or effect an abandonment in whole or in part unless such agreement is in writing and signed by the party against whom enforcement of the change, modification, discharge or abandonment is sought.
- 37. Applicable Law. The laws of the State of Maryland shall govern the validity, performance and enforcement of this Lease.
- 38. Transfer of the Property. In the event of the sale or other transfer of Landlord's right, title and interest in the Leased Premises or the Property (except in the case of a sale- leaseback financing transaction in which Landlord is the lessee), Landlord shall transfer and assign to such purchaser or transferee all amounts of pre-paid Minimum Annual Rent and Additional Rent, and provided that the purchaser or transferee shall assume all of the surviving liabilities and obligations of Landlord hereunder accruing after the consummation of such sale or transfer, Landlord thereupon shall be released from all liability and obligations hereunder derived from this Lease arising out of any act, occurrence or omission relating to the Leased Premises or this Lease occurring after the consummation of such sale or transfer. Tenant shall have no right to terminate this Lease, to abate Minimum Annual Rent or Additional Rent, nor to deduct from, nor set-off, nor counterclaim against Minimum Annual Rent or Additional Rent because of any sale or transfer (including, without limitation, any sale-leaseback) by Landlord or its successors or assigns.
- 39. Extension Option. Provided (i) that this Lease shall be in full force and effect; (ii) that BTRL Contracts and Services, Inc. (or a permitted assignee of Tenant [which is a related party to Tenant] pursuant to the provisions of Section 15 hereof) shall be the tenant hereunder; and (iii) that Tenant shall not be in default under any of the terms, provisions, covenants or condition of this Lease, then, and only in such event, Tenant shall have the right, at Tenant's sole option, to extend the term of this Lease for two (2) additional periods of five (5) years each ("Extension Terms"). Each such extension option shall be exercisable by Tenant giving written notice of the exercise of such extension option to Landlord no sooner than three hundred sixty-five (365) days and no later than one hundred eighty (180) days prior to the expiration date of the then-current term; provided, however, in the event Tenant fails to exercise any option to extend during the aforesaid period such extension option shall become null and void and all rights with respect thereto and with respect to any subsequent extension option shall become null and void and all rights with respect

terminate and expire. Each Extension Term shall be upon the same terms, covenants and conditions as set forth herein with respect to the Lease Term, except that Minimum Annual Rent payable during each Lease Year of each Extension Term shall be computed in the following manner. On the first day of the first Lease Year of the first Extension Term, and on the first day of each Lease Year thereafter during the remainder of the first Extension Term and during the Second Extension Term, the Minimum Annual Rent (then in effect) shall be adjusted by one hundred percent (100%) of any change in the Index now known as "United States Bureau of Labor Statistics, Consumer Price Index for All Urban Consumers, All Items (1982-1984=100)" ("Index"), provided, however, that the amount of Minimum Annual Rent payable by Tenant during any Lease Year of an Extension Term pursuant to this provision shall not be less than one hundred three percent (103%) of the Minimum Annual Rent paid during the previous Lease Year. Subject to the foregoing, each such adjustment shall be accomplished (and shall be effective for the entire then- operative Lease Year) by adding to the Minimum Annual Rent (then in effect) the amount created by multiplying the Minimum Annual Rent then in effect by the amount created by subtracting one (1) from a fraction, the numerator of which shall be the most recently published monthly Index figure prior to the date of the adjustment, and the denominator of which shall be the published monthly Index figure for the same month of the previous year. Landlord shall give Tenant written notice of each such adjustment and the amount of Minimum Annual Rent payable during the forthcoming Lease Year. Should said Index cease to be published, then the closest similar published Index by an agency of the United States Government shall be substituted. Should there be no such substitute, then the parties hereto shall, under rules of the American Arbitration Association, agree to a substitute formula, or source, designed to accomplish the same original purpose of this provision. This extension option is personal to Tenant, and shall not be available to any other subtenant or assignee of the Lease (other than a party which is related to Tenant), regardless of whether such sublease or assignment was approved by Landlord in the manner described herein.

40. Right of First Offer. In the event that, during the Lease Term, Landlord determines to sell the Property to any party which is unrelated to Landlord, then, provided that (i) this Lease shall be in full force and effect; (ii) that BTRL Contracts and Services, Inc. (or a permitted assignee of Tenant [which is a related party to Tenant] pursuant to the provisions of Section 15 hereof) shall be the tenant hereunder; and (iii) Tenant shall not be in default under any of the terms, provisions, covenants or conditions of this Lease, then, and only in such event, Tenant shall have the first right to purchase the Property upon the following terms and conditions. Promptly after determining the terms and conditions upon which the Property shall be sold to a third party, Landlord shall give Tenant written notice of its opportunity to purchase same, by presenting Tenant with an execution copy of a Contract of Sale for the Property containing all material terms and conditions as determined by Landlord to be appropriate for the sale of the Property. Tenant shall exercise its right of first offer by executing the copy of the Contract of Sale tendered by Landlord and returning it to Landlord (together with any required earnest money deposit) within thirty (30) calendar days of the date on which Landlord delivered the proposed Contract of Sale to Tenant. The failure of Tenant to execute and deliver the Contract of Sale (and required earnest money deposit) to Landlord within the aforesaid thirty (30) calendar day period shall automatically extinguish Tenant's right to exercise such right of first offer with regard to the Property, and further shall relieve Landlord of any and all liability with respect to same; provided that such right of first offer shall be reinstated, without further act required by any party, in the event that Landlord has not settled on the sale of the Property within three hundred sixty-five (365) days of the expiration date of Tenant's right of first offer as described

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herein. Notwithstanding the foregoing, Landlord shall not thereafter offer to sell the Property to any third party for a purchase price which is less than that offered to Tenant or upon such other material terms and conditions which are substantially less advantageous to the purchaser, without first renewing its offer to Tenant to purchase same at the lesser amount of purchase price (and

affording Tenant the right to exercise its first right of offer in the manner described herein). Should Tenant fail to exercise properly its right of first offer as described above, Landlord shall be free to proceed with the sale of the Property to any third party, free and clear of all rights of Tenant; provided that such right of first offer shall be reinstated, without further act required by any party, in the event that Landlord has not settled on the sale of the Property within three hundred sixty-five (365) days of the expiration date of Tenant's right of first offer as described herein. In the event that Tenant exercises its right of first offer as provided herein, then Landlord and Tenant shall proceed to settlement thereunder in accordance with the terms and conditions of the Contract of Sale. In the event that Tenant thereafter fails to settle on its purchase of the Property in accordance with the terms and conditions of the Contract of Sale, then Landlord shall have the right (but not the obligation), as determined in its sole and absolute discretion, to terminate this Lease, in addition to exercising any and all rights available to it pursuant to the terms and conditions of the Contract of Sale. Landlord shall exercise its right to terminate this Lease by giving written notice thereof to Tenant, in which event this Lease shall terminate on the third day after the giving of such notice, and Tenant shall deliver possession of the Leased Premises to Landlord. This right of first offer is personal to Tenant, and shall not be available to any other subtenant or assignee of the Lease (other than a party which is related to Tenant), regardless of whether such sublease or assignment was approved by Landlord in the manner described herein.

41. Right of First Refusal. Provided (i) that Landlord has not offered Tenant the right to purchase the Property for a purchase price which is equal to or less than the offer described below and is upon such material terms and conditions which are substantially the same or more advantageous to the purchaser than are contained in the offer described below, and that Tenant's right of first offer has not expired (and Tenant's right under Section 40 has not been reinstated), all pursuant to the terms and conditions of Section 40 hereof; (ii) that this Lease shall be in full force and effect; (iii) that BTRL Contracts and Services, Inc. (or a permitted assignee of Tenant [which is a related party to Tenant] pursuant to the provisions of Section 15 hereof) shall be the tenant hereunder; and (iv) that Tenant shall not be in default under any of the terms, provisions, covenants or condition of this Lease, then, and only in such event, Tenant shall have the right of first refusal to purchase the Property (the "Right of First Refusal") upon the following terms: If at any time during the Lease Term, Landlord shall receive a bona fide offer from a third party for the purchase of the Property, which offer Landlord desires to accept, Landlord promptly shall deliver to Tenant a copy of such offer. Tenant may, within thirty (30) days after receipt of such offer, elect to purchase the Property on the same terms and conditions as set forth in such offer, by delivering to Landlord written notice of said exercise within the aforesaid thirty (30) day period. In the event that Landlord shall receive an offer for the purchase of the Property which is not consummated by delivering a deed to the offeror, Tenant's Right of First Refusal as set forth herein shall remain applicable to subsequent offers made to Landlord. In the event that Landlord shall sell the Property after Tenant fails to exercise its Right of First Refusal, such sale shall be subject to the terms of this Lease, provided, however, the Right of First Offer and the Right of First Refusal as set forth in this Lease shall expire upon the date of conveyance of the Property to said third party, and said rights shall not continue in force or effect, nor shall they be applicable to any

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subsequent sale or ownership of the Property by successive parties. In the event that any mortgagee or holder of a deed of trust or other security interest in the Property shall foreclose on the Property or accept a deed in lieu of foreclosure as a result of the failure of Landlord to pay any debt secured by the Property, the Right of First Offer and the Right of First Refusal as set forth in this Lease shall expire automatically upon the date of conveyance of the Property to said mortgagee or holder of a security interest therein (or to any third party assignee of said mortgagee or holder of a security interest therein), and said Right of First Offer and the Right of First Refusal shall not continue in force or effect, nor shall they be applicable to any subsequent sale

or ownership of the Property by successive parties.

- 42. Waiver of Counterclaim and Trial by Jury/Attorneys Fees. Landlord and Tenant waive their right to trial by jury in any action, proceeding or counterclaim brought by either of the parties hereto against the other (except for personal injury or property damage) on any matters whatsoever arising out of or in any way connected with this Lease, the relationship of Landlord and Tenant, Tenant's use of or occupancy of the Leased Premises, and any emergency statutory or any other statutory remedy. Tenant shall not interpose any counterclaim(s) or claim(s) for set-off, recoupment or deduction of Minimum Annual Rent or Additional Rent in a summary proceeding for nonpayment of Minimum Annual Rent or Additional Rent, unless such counterclaim is mandatory in nature and must be interposed in such summary proceeding initiated by Landlord or otherwise be deemed waived. In the event either Landlord or Tenant institute an action or proceeding against the other to enforce the terms and conditions of this Lease, the prevailing party shall be entitled to recover all reasonable attorneys fees and costs incurred as a result thereof.
- 43. Separability. If any term or provision of this Lease or the application thereof to any person or circumstances shall, to any extent, be invalid or unenforceable, the remainder of this Lease or the application of such term or provision to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each other term and provision of this Lease shall be valid and enforceable to the fullest extent permitted by law.
- 44. Corporate Authority. Concurrently with the execution of this Lease, Tenant has delivered to Landlord a certified copy of a resolution of Tenant's Board of Directors (or other evidence reasonably satisfactory to Landlord) approving the leasing of the Leased Premises by Tenant pursuant to the terms and conditions contained herein, stating that this Lease is fully binding upon Tenant, and authorizing the execution of this Lease by each person signing this Lease on behalf of Tenant.

## 45. Interpretation.

- (a) Captions. The captions, marginal references, General Information sheet, and table of contents appearing in this Lease are inserted only as a matter of convenience and in no way amplify, define, limit, construe, or described the scope or intent of this Lease nor in any way affect this Lease.
- (b) Gender. The neuter, feminine or masculine pronoun when used herein shall each include each of the other genders and the use of the singular shall include the plural.
- (c) Covenants. The parties hereto agree that all the provisions of this Lease are to be construed as covenants and agreements as though the words importing such covenants and agreements were used in each separate provision hereof.
- (d) Interpretation. Although the printed provisions of this Lease were drawn by Landlord, this Lease shall

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not be construed for or against Landlord or Tenant, but this Lease shall be interpreted in accordance with the general tenor of the language in an effort to reach the intended result.

46. Landlord's Agreement re: Contract of Sale of the Property. Landlord agrees that, during the Lease Term and prior to its execution of any contract for the sale of the Property to a prospective purchaser, it shall give written notice of the existence of this Lease and Tenant's occupancy rights in and to the Leased Premises (together with a copy of this Lease), to any such prospective purchaser of the Property.

- 47. Reasonableness of Expenses. Wherever it is required by the terms of this Lease that one party reimburse the other party for costs and expenses incurred in connection with the performance of an obligation or the exercise of a right described herein, unless expressly stated otherwise, all costs and expenses for which such reimbursement is sought shall be reasonable in amount and nature, as determined in accordance with local standards of commercial reasonableness in the District of Columbia metropolitan area.
- 48. Limits of Landlord's Liability. In the event that any mortgagee or holder of a deed of trust or other security interest in the Property shall foreclose on the Property or accept a deed in lieu of foreclosure as a result of the failure of Landlord to pay any debt secured by the Property, then, thereafter, neither the owner of the Property, as Landlord, nor its agents, employees or officers, whether disclosed or undisclosed, shall have any personal liability under any provision of this Lease, and if such a subsequent owner of the Property, as Landlord, defaults in the performance of any of its obligations hereunder or otherwise, Tenant shall look solely to Landlord's equity, interest and rights in the Property for satisfaction of Tenant's remedies on account thereof.
- 49. Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto, and the heirs, personal representatives, successors and assigns of said parties.

IN WITNESS WHEREOF, the parties hereto have duly executed, sealed, and delivered this Lease, or have caused same to be executed, sealed and delivered by their duly authorized attorney-in-fact, as of the day and year above written.

WITNESS LANDLORD:

Cambridge Biotech Corporation, a Delaware corporation

By: /s/ signature unreadable (SEAL)
------/s/ signature unreadable

Date of Execution: July 14, 1992

WITNESS/ATTEST:

TENANT:

BTRL Contracts and Services, Inc., a Massachusetts corporation

/s/ signature unreadable

By: /s/ signature unreadable (SEAL)

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/s/ signature unreadable, President

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Date of Execution: July 14, 1992

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**EXHIBIT C** 

**RULES AND REGULATIONS** 

Tenant agrees as follows:

1. Tenant will keep the Leased Premises and approaches thereto clean and free from rubbish; will remove snow, ice and debris from the adjacent

sidewalks; will keep all windows and any sign neat, clean and in good order; will not erect any screen or fence; and will not perform any acts or carry on any practices which may damage the Leased Premises or the Property or be a nuisance or menace to other tenants.

- 2. Tenant shall not obstruct or interfere with the rights of others to use any Property driveways, parking facilities, sidewalks, exits, entrances, if any.
- 3. Tenant shall not store any material, supplies, equipment, wooden pallets, vehicles or anything whatsoever outside of the Leased Premises. If any such items are not removed within forty-eight (48) hours Landlord shall have the right to remove the same, with prior notice to Tenant, and with no responsibility to Tenant for loss or damage to such items, and the cost to Landlord of such removal shall be deemed to be Additional Rent under the Lease and will be immediately paid by Tenant to Landlord upon demand.
- 4. Business and mechanical equipment which cause noise or vibration that may be transmitted to the structure of the Leased Premises or to any space therein to such a degree as to be objectionable to Landlord or any other tenant of the Property, shall be placed and maintained by Tenant, at Tenant's expense, on vibration eliminators or other devices sufficient to eliminate noise or vibration.
- 5. Tenant shall comply with any governmental energy-saving rules, laws or regulations of which Tenant has notice.
- 6. The sewage system shall not be used for any purpose other than that for which it was constructed and no foreign substance of any kind whatsoever shall be thrown therein. The expense of any breakage, stoppage or damage resulting from the violation of this rule shall be borne by the Tenant who, or whose employees or invitees, shall have caused it.
- 7. Should the Tenant, its agents or invitees, activate its sprinkler system (if there is one in the Leased Premises), Tenant agrees that it will pay, as Additional Rent to Landlord, any damage to the Leased Premises and to property of other Property tenants.
- 8. All trash and garbage shall be kept within the Leased Premises (or in a dumpster placed on the common areas of the Property at a location reasonably satisfactory to Landlord) and collected on a regular basis. Tenant shall not place in any trash box or receptacle any material which cannot be disposed of in the ordinary and customary manner of trash and garbage disposal.
- 9. Tenant shall comply with all safety, fire protection and evacuation procedures and regulations established by or any governmental agency having jurisdiction.
- 10. Tenant assumes any and all responsibility for protecting the Leased Premises from theft, robbery and pilferage which includes keeping doors locked and other means of entry to the Leased Premises closed.
- 11. Tenant shall keep the inside and the outside of all glass in the doors and windows within the Leased Premises clean, keep all exterior surfaces of the Leased Premises clean, replace

promptly any cracked or broken glass of the Leased Premises with glass of like kind, color, and quality.

- 12. Tenant shall be responsible for the observance of all the foregoing rules by Tenant's employees, agents, clients, customers, invitees and guests.
- 13. Tenant shall give Landlord immediate notice in case of fire or accidents in the Leased Premises, and in case of fire or accidents on the Property involving Tenant, its agents, employees or invitees.

#### **GUARANTY**

In consideration of, and as a material inducement to Cambridge Biotech Corporation, a Delaware corporation qualified to do business in the State of Maryland, with a business and mailing address at 1500 East Gude Drive, Rockville, MD 20850 (the "Landlord"), executing and delivering simultaneously herewith, in reliance upon this Guaranty, that certain Lease (the "Lease"), dated as of June 30, 1992, between Landlord and BTRL Contracts and Services, Inc., a Massachusetts corporation qualified to do business in the State of Maryland ("Tenant"), the undersigned, Boston Biomedica, Inc., a Massachusetts corporation (the "Guarantor"), with a business and mailing address at 375 West Street, West Bridgewater, Massachusetts 02379, hereby unconditionally and absolutely guarantees unto Landlord, its successors and assigns, the full, prompt and complete payment by Tenant of the Minimum Annual Rent and Additional Rent provided in the Lease, and the prompt, faithful and complete performance and observance by Tenant of all of the terms, covenants and conditions of the Lease on the Tenant's part to be performed and/or observed. Upon the failure of Tenant to make any such payment of Minimum Annual Rent or Additional Rent provided in the Lease, or to perform or observe any such term, covenant or condition of the Lease on the Tenant's part to be performed and/or observed, Guarantor shall, promptly upon demand, pay such required sum to Landlord, or perform or observe the required term, covenant or condition of the Lease.

Guarantor does hereby waive notice of any and all defaults on the part of the Tenant, waives acceptance and notice of acceptance of this Guaranty, and waives all demand for payment and/or performance; and Guarantor agrees that no delay on the part of Landlord in enforcing any of its rights or remedies or insisting thereupon, nor any extension of time nor any changes or modifications in or to, or in connection with the Lease, shall in any way limit, affect or impair the liability of Guarantor hereunder; and Guarantor hereby expressly consents to and approves thereof with the same force and effect as though its written consent had been given to each of such delays, extensions, changes and modifications.

This Guaranty is independent of and in addition to any security or other remedies which Landlord has or may have for the performance of any of the obligations on the part of Tenant; and Guarantor agrees that Landlord shall not be required to resort to any other security or other remedies before proceeding upon this Guaranty, but that Landlord may proceed hereunder against Guarantor at any time it sees fit, independently of or concurrently with any other remedies it may have.

This Guaranty shall remain in full force and effect notwithstanding the institution by or against Tenant, of bankruptcy, reorganization, readjustment, receivership or insolvency proceedings of any nature, or the disaffirmance of the Lease in any such proceedings or otherwise.

If Guarantor is a corporation and is merged into or with any other company, firm or corporation, the resulting merged company, firm or corporation shall become liable as Guarantor under this Guaranty to the same extent as the original named Guarantor hereunder.

Concurrently with the execution of this Guaranty, Guarantor has delivered to Landlord a certified copy of a resolution of its Board of Directors (or other evidence reasonably satisfactory to Landlord) approving the guaranty by Guarantor of Tenant's obligations contained in the Lease pursuant to the terms and conditions contained herein, stating that this Guaranty is fully binding upon Guarantor, and authorizing the execution of this Guaranty by each person signing this Lease on behalf of Guarantor.

This Guaranty shall be binding upon the undersigned, the undersigned's successors and assigns, and shall inure to the benefit of Landlord, its successors and assigns, and to the benefit of any successors to the interest of Landlord under the Lease and/or to the Leased Premises.

IN WITNESS WHEREOF, the undersigned has duly executed this Guaranty under seal as of the 30th day of June, 1992.

WITNESS/ATTEST: GUARANTOR:

Boston Biomedica, Inc.

/s/ signature unreadable By: /s/ signature unreadable (SEAL)

Secretary Name: /s/ signature unreadable

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Title: President

State of UNREADABLE

County of UNREADABLE

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On this the 14th day of July, 1992, before me, the subscriber, a Notary Public in and for the jurisdiction aforesaid, personally appeared UNREADABLE who acknowledged himself/herself to be the President of Boston Biomedica, Inc., a Massachusetts corporation, and that he/she, as such President, being authorized so to do, executed the foregoing and annexed Guaranty for the purposes contained therein, by signing the name of the corporation by himself/herself as President.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

/s/ signature unreadable

Notary Public

My Commission Expires 11/6/92

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BTRL Contracts and Services, Inc. 375 West Street West Bridgewater, Massachusetts 02379

> Re: Lease Agreement Dated as of June 30, 1992 between Cambridge Biotech Corporation and BTRL Contracts and Services, Inc., covering certain premises known as 3 Taft Court, Rockville, Maryland 20850

## Gentlemen:

Reference is made to the above-reference Lease Agreement (the "Lease"), pursuant to which Cambridge Biotech Corporation ("Landlord") has leased certain premises known as 3 Taft Court, Rockville, Maryland, to be BTRL Contracts and Services, Inc. ("Tenant").

In mutual consideration of Landlord and Tenant entering into the above-referenced Lease, this will confirm that Landlord and Tenant have agreed to supplement the provisions of the Lease as follows:

1. Landlord and Tenant have agreed to clarify the provisions of Section 4(b)(iii), relating to insurance, so as to clarify in the third paragraph thereof that in the event that Landlord

causes its insurance carrier to provide a written statement reflecting the allocation of premiums paid by Landlord attributable to the Leased Premises (as defined therein) and the premiums attributable to the insurance carried on other properties owned by Landlord, the premiums attributable to the Leased Premises shall be Tenant's Proportionate Share of insurance costs payable under the Lease.

- 2. Landlord has agreed to provide to Tenant, on a quarterly basis, true and complete copies of bank statements reflecting the status of accounts in which monies have been deposited in escrow on account of real estate taxes pursuant to Section 4(b)(ii) of the Lease, insurance premiums pursuant to Section 4(b)(iii) of the Lease, and the Security Deposit pursuant to Section 5 of the Lease.
- 3. In the event that Landlord refinances the real property of which the Leased Premises constitute a part, Landlord agrees to modify and amend the Lease so as to eliminate the limitations on the Landlord's (and any subsequent owner's) liability pursuant to Section 48 of the Lease, unless Landlord's prospective new mortgage lender, if any, refuses (in its sole discretion) to finance the property if such modification or amendment is made.

EXECUTED as a sealed instrument as of the 30th day of June, 1992.

TENANT:	LANDLORD:

BTRL CONTRACTS SERVICES, INC. CAMBRIDGE BIOTECH CORPORATION

BY: /s/ signature unreadable BY: /s/ signature unreadable

Vice President

## EXHIBIT 10.8

LEASE

BY AND BETWEEN

MB ASSOCIATES

AND

# BBI - NORTH AMERICAN CLINICAL LABORATORIES, INC.

75 NORTH MOUNTAIN ROAD NEW BRITAIN, CONNECTICUT

DATED AS OF JULY 28, 1995

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#### **EXHIBITS**

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Exhibit A - Plan of Demised Premises Exhibit B - Schedule of Landlord's Work Exhibit C - Rules and Regulations

LEASE

THIS LEASE made as of the 28th day of July, 1995, by and between MB ASSOCIATES, a Connecticut partnership having its office at Plainville, Connecticut (the "Landlord", and BBI- NORTH AMERICAN CLINICAL LABORATORIES, INC., a Massachusetts corporation having an address of 75 North Mountain Road, New Britain, Connecticut (the "Tenant").

#### Demise - Premises - Term.

- (a) The Landlord hereby demises and leases to the Tenant, and the Tenant hereby takes and hires from the Landlord, for the term hereinafter stated, for the rent hereinafter reserved, and upon and subject to the covenants, agreements, terms, conditions, limitations, exceptions and reservations of this lease, the building known as 75 North Mountain Road, New Britain, Connecticut, together with the exclusive use of the parking area and land shown and described in Exhibit A, attached hereto and made a part hereof (the "Demised Premises).
- (b) The term of this lease and the estate hereby granted (collectively the "term of this Lease") shall commence on the Commencement Date (as defined in section 1(c)) and shall end on the last day of the calendar month in which occurs the day preceding the fifth (5th) anniversary of the Commencement Date, which ending date, unless the context otherwise requires, is hereinafter called the "Expiration Date", or shall end on such earlier date upon which the term of this lease may expire or be terminated pursuant to any of the provisions of this lease or pursuant to law.
- (c) The term "Commencement Date: shall be that date when the Demised Premises are ready for occupancy by the Tenant, or on August 1, 1995, whichever date shall occur later, and all of the following conditions are met: (i) temporary or final certificate of occupancy shall have been issued by the City of New Britain permitting the activities specified in Section 5 to be conducted in the Demised Premises; (ii) the contractor engaged by the Landlord has issued a certificate attesting that the Landlord's Work (as defined in section 4(b)) has been substantially completed; and (iii) the Landlord's Work has been substantially completed, and it shall be deemed to be substantially completed notwithstanding the fact that minor or insubstantial details of construction, mechanical adjustment or decoration remain to be performed, the noncompletion of which does not interfere materially with the Tenant's normal use and occupancy of the Demised Premises, provided, however, that if substantial completion of the Landlord's Work shall be delayed beyond July 31, 1995, because of changes in the Landlord's Work at the request of the Tenant as provided in Section 4(c) (within fifteen (15) days after the delivery of any such change request, the Landlord shall notify the Tenant

Initials	
	(Landlord)
	(Tenant)

whether or not such change request is likely to cause a delay in the completion of the Landlord's Work beyond July 31, 1995) then the Commencement Date shall be deemed to be August 1, 1995, provided all other work has been substantially completed, even though the conditions set forth in this Section 1(c) shall not have been satisfied.

#### 2. Rent.

- (a) The rent reserved under this lease (the "Rent") for the term hereof shall commence to accrue on the Commencement Date and shall be:
  - (i) Annual Fixed Rent For the First Year, \$125,200.00
  - (ii) Annual Fixed Rent For the Second Year, \$132,700.00
  - (iii) Annual Fixed Rent For the Third Year, \$140,200.00
  - (iv) Annual Fixed Rent For the Fourth Year, \$147,700.00
  - (v) Annual Fixed Rent For the Fifth Year, \$155,200.00
  - (vi) such other sums of money as shall become due and payable by the Tenant to the Landlord as provided in this lease, such other sums of money to be deemed to be additional rent whether or not such sums of money are designated as such hereunder.
- (b) The Rent shall be paid to the Landlord at its address specified in Section 27, or at such other place as the Landlord may from time to time designate, in lawful money of the United States of America, as and when the same shall become due and payable and without abatement or offset and without notice or demand therefor.
- (c) The annual Fixed Rent for each lease year shall be payable in equal monthly installments in advance on the first day of each and every calendar month during each lease year. If the Commencement Date is other than the first day of the calendar month, the first monthly installment of the Fixed Rent shall include a pro rata installment of Fixed Rent for the period from the Commencement Date to the last day of the month in which the Commencement Date occurs based upon the Fixed Rent payable during the term hereof.

Initials	
	_ (Landlord)
	_ (Tenant)

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(d) If the Tenant fails to pay within ten (10) days after the same is due and payable any installment of Fixed Rent or any additional rent to be paid by the Tenant to the Landlord as provided in this lease, such unpaid amount shall bear interest from the due date thereof to the date of payment at the rate equal to the lesser of (i) twelve percent (12%) per annum, or (ii) the maximum rate permitted by applicable law. Such interest shall be paid by the Tenant to the Landlord on the earlier to occur of A) at the time that the Tenant pays to the Landlord the installment of Fixed Rent or the additional rent upon which such interest shall have accrued or (B) five (5) days after written demand

therefor.

- (e) As used herein, the term "lease year" shall mean the period commencing on the Commencement Date and ending on the last day of the calendar month in which occurs the day preceding the first (1st) anniversary of the Commencement Date, and each period of twelve (12) consecutive calendar months thereafter.
- (f) If, on the Grand Lists of 10/1/95, 10/1/96, 10/1/97, 10/1/98 and 10/1/99, as a result of Tenant's use of the Demised Premises, the City of New Britain provides real property tax abatement for the Demised Premises, the rent reserved in Section 2(a), above, will be reduced by an amount equal to the amount of tax abatement received, but in no event less than Six Thousand Dollars (\$6,000.00) per year for the 2nd through the 5th year of the Term, and the first year of the first renewal term of this Lease.

The parties agree to execute an amendment to this Lease establishing the fixed annual rent in the event of such tax abatement and to establish the annual fixed rent for the renewal terms set forth in Sections 3 (a) and (b).

## 3. Renewal Options:

- (a) Tenant shall have the option to renew this Lease for a term of five (5) years on the same terms and conditions as provided herein except that the annual fixed rent for each year during said first renewal term shall be the greater of (i) \$161,230 or (ii) \$140,200.00 plus the cumulative percentage of increase, if any, in the Consumer Price Index All Item Figures for Urban Wage Earners and Clerical Workers (N.Y., Northern N.J., Long Island, N.Y, NJ, CT) (1982-94 = 100) published by the Bureau of Labor Statistics, U.S. Department of Labor as of the date of the commencement of the first renewal period over the said Index as of the date of the commencement of the initial term of this Lease, which increase shall not exceed 25%.
- (b) Tenant shall have a further option to renew this Lease for an additional term of five

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	_ (Landlord)
	_ (Tenant)

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- (5) years on the same terms and conditions as provided herein except that there shall be no further right of renewal and that the annual fixed rent for each year of said second renewal term shall be the greater of (i) an amount equal to the annual fixed rent during said first renewal term plus fifteen percent (15%) or (ii) the annual fixed rent during said first renewal term plus the cumulative percentage of increase, if any, in the Consumer Price Index All Item Figures for Urban Wage Earners and Clerical Workers (N.Y., Northern N.J., Long Island, N.Y, NJ, CT) (1982-94 = 100) published by the Bureau of Labor Statistics, U.S. Department of Labor as of the date of the commencement of the second renewal period over the said Index as of the date of the commencement of the first renewal period of this Lease, which increase shall not exceed 25%.
- (c) The Tenant's right to exercise its options to renew hereunder shall be contingent upon (i) the Tenant's giving to the Landlord notice of the Tenant's election to exercise its option to renew not later than nine (9) months prior to the expiration date of the initial term or first renewal term, as the case may be, of this Lease and (ii) the term of this lease being in full force and effect on the date that the Landlord receives notice of the Tenant's election to exercise its option to renew and on the expiration date of the initial term or first renewal term as the case may be of this lease. If such contingencies shall be satisfied in respect to the exercise of the Tenant's options to renew hereunder, then the renewal period shall be added to and become part of the term of this lease and any reference in this lease to "term of this lease"; the "term hereof" or any similar expression shall be deemed to include such renewal period.

- (d) If at any time the Landlord shall be restricted or prevented by virtue of any law, rule, regulation or order, such as a "Wage-Price-Rent Freeze", from obtaining the full amount of the Rent for such renewal term, then on any occasion upon which it becomes lawful to obtain and receive the balance (or any part thereof) of the full rent payable, the Fixed Rent payable hereunder shall be increased by the maximum amount lawful until the full Fair Market Rental Value for such renewal period is received by the Landlord.
- (e) A memorandum recording the amount of the rent payable for such renewal period shall be annexed hereto and signed by the Landlord and the Tenant promptly upon the same being agreed or determined in accordance with the terms hereof.
  - 4. Construction by the Landlord.
- (a) The Landlord may make such improvements or additions to the Demised Premises and its appurtenances as the Landlord shall see fit except that the Landlord shall secure the prior written approval of the Tenant, which approval shall not be unreasonably withheld or delayed, in the

Initials	
	_ (Landlord)
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case of any change, addition or deletion which materially and adversely affects the visibility, access of or to Tenant's use of the Demised Premises for the purposes set forth in Section 5 or any other rights of the Tenant under this lease.

- (b) The Landlord shall perform work and make installations in the Demised Premises in a good and workmanlike manner and in accordance with the plans and specifications set forth in Exhibit B attached hereto. (All of the work to be performed by the Landlord pursuant to this Section 4(b) is referred to as the "Landlord's Work").
- (c) The Tenant may make written requests for changes in the Landlord's Work, and the Landlord shall comply with any such request that in the Landlord's judgment is not unreasonable. Any change in the scope of the Landlord's Work which would result from such a request and which would unreasonably interfere with or delay the work of the Landlord's contractors and subcontractors in the Demised Premises or elsewhere in or about the building shall be conclusively deemed unreasonable. Any increase in the Landlord's cost of construction of the Landlord's Work resulting from such a request shall be acknowledged in writing by the Tenant prior to the performance of the change in the Landlord's Work. Any net increase arising from all such changes in the Landlord's Work shall be paid by the Tenant to the Landlord, as additional rent, within ten (10) days after the Landlord's written demand. The Tenant shall not be entitled to any payment from the Landlord, or to any credit against or reduction in the Rent, on account of any net decrease arising from all such changes in the Landlord's Work.
- (d) The Tenant, by entering into actual possession of any part or parts of the Demised Premises, shall be deemed to have agreed that the Landlord, up to the time of such possession, has performed all of its obligations hereunder with respect to preparation of such part or parts of the Demised Premises for the Tenant's possession, except for (i) latent defects and (ii) minor items remaining incomplete. The Tenant, within sixty (60) days after the Commencement Date, shall give the Landlord written notices of any incomplete work, unsatisfactory conditions or defects, and the Landlord shall repair or replace all materials and workmanship, fixtures, systems, facilities and equipment installed by the Landlord in or serving the Demised Premises which prove to be defective, and shall prosecute those items remaining incomplete to completion with reasonable diligence.

Premises for a medical laboratory, clinical laboratory, biomedical manufacturing, biomedical repository, research and general office purposes, and the Tenant shall not use or permit the use of the Demised Premises for any other purpose.

Initials	
	(Landlord)
	(Tenant)

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6. Signs. Unless the Landlord shall have given its prior written consent, which consent shall not be unreasonably withheld, the Tenant shall not install, paint, inscribe or maintain any lettering, name, sign, business designation, advertising or publicity device on the Land or on any exterior window or on any other interior or exteriors portion of the building. All signage shall be consistent with a comprehensive sign plan for the planned area development of this North Mountain Road area and is contingent upon approval from all appropriate governmental agencies.

#### 7. Subordination of Lease.

Tenant agrees that upon the request of Landlord in writing it will subordinate this Lease and the lien hereof from time to time to the lien of any present or future mortgage to a bank, insurance company or similar financial institution, irrespective of the time of execution or time of recording of any such mortgage or mortgages, provided that the holder of any such mortgage shall enter into an agreement with Tenant, in recordable form, that in the event of foreclosure or other right asserted under the mortgage by the holder or any assignee thereof, this Lease and the rights of Tenant hereunder shall continue in full force and effect and shall not be terminated or disturbed except in accordance with the provisions of this Lease. Tenant agrees that if requested by the holder of any such mortgage it will be a party to said agreement and will agree in substance that if the mortgagee or any person claiming under the mortgagee shall succeed to the interest of Landlord in this Lease, it will recognize said mortgagee or person as its landlord under the terms of this Lease. Tenant agrees that it will upon the request of Landlord, execute, acknowledge and deliver any and all instruments necessary or desirable to give effect to or notice of such subordination. The word "mortgage" as used herein includes mortgages, deeds of trust or other similar instruments and modifications, consolidations, extensions, renewals, replacements and substitutes thereof.

Such subordination agreement shall include, but not be limited to, statements that if the lender or ground lessor succeeds to the interest of Landlord under this Lease, lender or ground lessor shall not be:

- (i) liable for any act or omission of any prior landlord (including Landlord) except for those acts or omissions which are continuing after lender succeeds to landlord's interest; or
- (ii)subject to any offsets or defenses which Tenant might have against any prior landlord (including Landlord); or

Initials	
	(Landlord)
	(Tenant)

- (iii) bound by any rent or additional rent which Tenant might have paid for more than the current month to any prior landlord (including Landlord).
- (b) If, in connection with the procurement, amendment or renewal of any financing of the Demised Premises, the mortgagee shall request reasonable modifications of this lease as a condition of such financing, the Tenant shall not withhold or delay its consent to such modifications provided that they do not increase the obligations of the Tenant under this lease or adversely affect the rights of the Tenant under this lease.
- 8. Quiet Enjoyment. The Landlord covenants and agrees that so long as the Tenant pays the Rent and performs the remainder of the Tenant's obligations under this lease, the Tenant shall peaceably and quietly have, hold, and enjoy the Demised Premises without interference by any person claiming by, through or under the Landlord.
  - 9. Assignments and Subleases.
- (a) Except as otherwise provided in this Section 9, the Tenant agrees not to assign or in any way encumber this lease, nor to sublet the Demised Premises, or any part thereof, nor to permit the Demised Premises, or any part thereof, to be used by others, without obtaining the prior written consent of the Landlord in each instance, which consent shall not be unreasonably withheld or delayed.
- (b) So long as no event of default shall have occurred and be continuing hereunder, the Tenant may assign this lease to any corporation or other entity into which the Tenant may be merged or with which the Tenant may be consolidated, or to which all or substantially all of the Tenant's assets shall be transferred, provided that such corporation or other entity shall have a net worth at least equal to that of the Tenant immediately prior to such merger, consolidation or transfer. The Tenant shall give notice to the Landlord of any assignment under this Section 9(b), and shall deliver to the Landlord an executed counterpart of the instrument effecting such assignment, together with an undertaking by any such corporation or other entity to agree to be bound by and to perform all of the Tenant's obligations hereunder.
  - (c) (Left Intentionally Blank)
- (d) No assignment or subletting of this lease shall relieve the Tenant of any of the Tenant's obligations under this lease, unless otherwise agreed to in writing by Landlord.

Initials	
	_ (Landlord)
	(Tenant)

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- (e) Notwithstanding Subparagraph 9(a) above, until such time as Tenant is able to utilize the entire floor space of the building of the Demised Premises, Tenant may sublet that portion of the building which it does not use for its business purposes, with Landlord's prior written approval which shall not be unreasonably withheld or delayed, subject, however, to the following conditions:
  - 1. Sublessee shall be of good reputation and financial responsibility.
- 2. Character of business to be conducted by such sublessee shall be reasonably acceptable to Landlord, and the premises shall be used only for a

purpose allowed in Section 5 above and shall be in keeping with the character, standing, and quality of the building.

- 3. Any assignee or subleasee shall be bound by the terms of this Lease, including Schedule C hereto.
- 4. Tenant shall not be released by reason of such subletting from the due, prompt, and punctual performance of all of the terms, covenants, and conditions contained in this lease to be performed on its part and from the payment of the rents and additional rents herein reserved.
- 5. Landlord's consent to such subletting shall not constitute a waiver of any provision of this agreement and no further subletting shall be made without Lessor's written consent. The sublessee shall not further assign, sublet, or underlet the premises without Landlord's prior written consent, and then only on compliance with all of the provisions contained in this Paragraph.
- 10. No Nuisance; Compliance with Laws and Requirements of Public Authorities. The Tenant agrees (a) not to create or permit any nuisance in or about the Demised Premises, (b) to comply with and conform to (i) all of the laws and regulations of the State of Connecticut, and (ii) the by-laws, ordinances, rules and regulations of the City of New Britain so far as the Tenant's use of the Demised premises may be concerned, and (c) to save the Landlord harmless from all damages, fines, penalties and costs for violation of or non-compliance by the Tenant or the Tenant's servants, employees, agents, customers, invitees, licensees, or visitors with the provisions of this Section 10 and obtain and keep in effect all permits required by governmental agencies for the operation of a medical laboratory, including, but not limited to, waste discharge permits from the Connecticut Department of Environmental Protection.

#### 11. Insurance.

(a) At all times during the term of this lease, the Landlord shall insure the building

Initials	
	(Landlord)
	(Tenant)

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against loss or damage by fire, and such other casualties as may be included within the extended coverage clauses of policies which are then standard for use in the State of Connecticut, in such amount as the Landlord in its sole judgment shall deem appropriate.

- (b) The Tenant shall not commit or permit any violation of the policies carried by the Landlord pursuant to Section 11(a), or do or permit anything to be done, or keep or permit anything to be kept, on or in the Demised Premises, which, in case of any of the foregoing (i) would result in termination of any of such policies, (ii) would adversely affect the Landlord's right of recovery under any of such policies, or (iii) would result in the refusal by reputable and independent insurance companies to insure the building or the property of the Landlord therein in amounts reasonably satisfactory to the Landlord. If any such action by the Tenant, or any failure by the Tenant to comply with the reasonable requirements of insurance policies with respect to the building or to perform any of the Tenant's obligations under this lease, or the use of the Demised Premises by the Tenant, shall result in any increase in the rate of premiums payable with respect to such policies carried by the Landlord, the Tenant shall pay to the Landlord, as additional rent, within ten (10) days after demand therefor, the resulting additional premiums which shall be paid by the Landlord, it being understood that such policies obtained by Landlord will permit without extra cost the uses described in Paragraph 5 above.
- (c) At all times during the term of this lease, the Tenant shall (i) insure the Tenant's Improvements (as defined in Section 13), but excluding all

fixtures and real property and the Tenant's Property (as defined in Section 14) against loss or damage by fire and such other casualties as may be included within the extended coverage clauses of policies which are then standard for use in the State of Connecticut in amounts at all times equal to the full replacement value of the Tenant's Improvements and the Tenant's Property, and (ii) keep in full force and effect a policy of public liability and property damage insurance with respect to the Demised Premises, the building and the Land in which the limits initially shall be not less than One Million Dollars (\$1,000,000.00) for each person and Three Million Dollars (\$3,000,000.00) for each accident, and in which the limit for property damage initially shall not be less than Two Hundred Fifty Thousand Dollars (\$250,000.00), such limits to be increased from time to time as reasonably specified by the Landlord. In addition, for and during any time when the Tenant shall be constructing or making Tenant's Improvements, the Tenant shall keep in full force and effect a policy of completed value builder's risk insurance (or an "installations floater") for the Demised Premises, covering loss or damage from fire, lightning, extended coverage, perils, vandalism and malicious mischief and perils in an amount not less than the final cost, as reasonably estimated by the Tenant, of such Tenant's Improvements.

(d) Each party hereto shall procure an appropriate clause in, or endorsement on, each of

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its policies for fire and extended coverage insurance covering the Demised Premises, the Tenant's Improvements, or the building or personal property, fixtures or equipment located thereon or therein, pursuant to which the insurance company waives subrogation or consents to a waiver of right of recovery against the other party, and if such a clause or endorsement of waiver of subrogation or consent to a waiver of right of recovery is obtained, such party hereby agrees that it will not make any claim against or seek to recover from the other for any loss or damage to its property or the property of others covered by such fire or extended coverage insurance; provided, however, that the release, discharge, exoneration and covenant not to sue herein contained shall be limited by the terms and provisions of the waiver of subrogation clause or endorsement or the clause or endorsement consenting to a waiver of right of recovery and shall be co-extensive therewith.

(e) All insurance provided by the Tenant pursuant to this Section 11 shall be effected under valid and enforceable policies in form and substance then standard in the State of Connecticut, issued by insurers of recognized responsibility licensed to do business in the State of Connecticut. Upon the Commencement Date, and thereafter not less than thirty (30) days prior to the expiration dates of expiring policies provided by the Tenant pursuant to this Section 11, the Tenant shall deliver to the Landlord copies of policies or certificates with respect to the insurance being maintained by the Tenant pursuant to the terms of this lease. All such policies or certificates shall contain an agreement by the insurers that such policies will not be canceled, amended or otherwise modified without at least thirty (30) days prior written notice to the Landlord, and that the Landlord's rights and interests under such polices shall not be subject to cancellation by reason of any act or omission of the Tenant. All insurance policies provided by the Tenant pursuant to this Section 11 shall name the Landlord and the Landlord's mortgage lenders as additional insureds as their interests may appear.

(f) The Tenant shall indemnify and hold the Landlord harmless against and from any liability or expense, including, without limitation, reasonable attorney's fees, on account of (i) any accident or injury to the Tenant, the Tenant's servants, employees, agents, customers, invitees, licensees, or visitors who may be injured or suffer an accident in the Demised Premises unless the same is caused by the negligence or willful act of the Landlord, or the

Landlord's servants, agents or employees, and (ii) the Tenant's activities in or use of the Demised Premises or elsewhere on the Land or in the building.

12. Rules and Regulations. The Tenant and its officers, employees and agents shall conform to and aide by such reasonable rules and regulations, including those Rules and Regulations as are set forth on Exhibit C attached hereto, as shall be established from time to time by the Landlord in connection with the operation, maintenance, safety and security of the Demised

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Premises. The Landlord shall not be liable to the Tenant for violation of such rules and regulations by others.

- 13. Alterations and Improvements.
- (a) The Tenant may make or have made interior alterations, improvements, decorations, installations and substitutions (collectively called "Tenant's Improvements"), to the Demised premises without the prior written consent of the Landlord, but shall make no structural alterations or exterior improvements or additions without the prior written consent of Landlord. Any improvements or alterations in the Demised Premises made by the Tenant (including, without limitation, permanent partitions, wall paneling and lighting fixtures, but excepting the Tenant's Property (as defined in Section 14)) shall be and remain the property of the Landlord and, except as provided in Section 20, shall remain upon and be surrendered with the Demised Premises at the termination of the term of this lease. If the Landlord consents to any such alterations, improvements or additions, it may impose such conditions with respect thereto as the Landlord reasonably deems appropriate, including, without limitations, requiring the Tenant to furnish the Landlord with security for the payment of all costs to be incurred in connection with such work, insurance against liabilities which may arise out of such work and plans, specifications and permits necessary for such work. Upon completion of such work the Tenant shall deliver to the Landlord, if payment is made directly to contractors, evidence of payment, contractors' affidavits and full and final waivers of all liens for labor, services of materials.
- (b) The Tenant, at its expense, shall obtain all necessary governmental permits and certificates for the commencement and prosecution of the Tenant's improvements (other than the Landlord's Work) and for final approval thereof upon completion, and shall cause the Tenant's Improvements (other than the Landlord's Work) to be performed in compliance therewith and with all applicable laws and requirements of public authorities, and in a good and workmanlike manner using only good grades of materials.
- (c) The Tenant's Improvements shall not constitute the basis for a claim against the Landlord, nor a lien or charge upon or against the Demised Premises, and if at any time any such claim, lien or charge shall be filed against the Demised Premises, the Tenant shall cause such claim, lien or charge to be properly released of record within forty-five (45) days after the filing thereof, and if the Tenant shall fail to do so, then the Landlord may discharge the same. The Tenant shall defend, indemnify and save harmless the Landlord from and against any and all such claims, liens and charges, and all costs and expenses, including reasonable attorney's fees, incurred by the Landlord in procuring the discharge of any such claim, lien or charge or in connection with any

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action or proceeding brought thereon.

(d) The Tenant shall pay for all materials, excluding Tenant's equipment and personal property constituting Tenant's Improvements, and the Tenant agrees that none of such materials that are incorporated into and made a part of the building or real estate shall be at any time subject to or encumbered by any lien, security interest, encumbrance, charge, installment sales contract or the interest of any other person, firm or corporation whether created voluntarily or involuntarily.

#### 14. Tenant's Property.

- (a) Except for Tenant's Improvements and those items furnished or installed by the Landlord as part of the Landlord's Work as provided in Section 4(b), all movable partitions, business machinery and equipment, communications equipment and all other property which is not attached to or built into the Demised Premises and which is installed in the Demised Premises by or for the account of the Tenant at its sole expense, and all furniture, furnishings and other articles of personal property owned by the Tenant and located in the Demised Premises (all of which are collectively called the "Tenant's Property"), shall be and shall remain the property of the Tenant, and shall be removed by it at the termination of the term of this lease. The Tenant shall repair or pay the cost of repairing any damage to the Demised Premises or to the building resulting from such removal.
- (b) The Landlord shall not be liable to the Tenant or any other person for any loss or damage to the Tenant's Property or the Tenant's Improvements, or to any property of any other person, from any cause, including, without limitation, theft, vandalism, illegal entry, or by steam, gases or electricity, or by water, rain or snow, whether the same may leak into, issue or flow from any part of the building, or from the pipes or plumbing work of the building, or from any other place or quarter, unless caused by the negligence or willful act of the Landlord, its servants, agents or employees.
  - 15. Tenant's Repairs, Cleaning & Utilities.
- (a) Except for the maintenance for which the Landlord is expressly responsible pursuant to the provisions of Section 16, the Tenant agrees that throughout the term of this lease, the Tenant, at its expense, shall (i) keep the interior of Demised Premises in a clean condition and in clean and neat condition, and (ii) not do or suffer any waste, damage in or to the Demised Premises or the Tenant's Improvements.
- (b) Except for loss or damage by reason of the causes set forth in Section 11(a), the

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Tenant shall reimburse the Landlord for all costs and expense incurred by the Landlord to repair all damage to the Demised Premises as shall be required by reason of the fault or neglect of the Tenant, or any of its officers, employees, contractors, agents or invitees, such payment to be made within ten (10) days after written demand therefor.

(c) Tenant shall provide its own janitorial services within the Demised Premises and shall pay for all utility charges related to the provision of hot and cold running water, electricity, heat, air conditioning and ventilation in the building on the Demised Premises. At the end of the first Lease year, the parties agree to review the costs of janitorial and utility services paid for by Tenant. Upon the signing of this Lease, the Tenant has estimated its janitorial costs to be \$7,800.00 per year and Landlord has estimated the utility costs, for a 5-day, 14-hour per day week, and a 1/2 day Saturday, to be \$42,000.00 per year. If the actual costs for utility services vary from the above estimate by more than five percent (5%), the parties agree to discuss in good faith modifying the amount of rent payable under this Lease in light of such variance. The parties shall consider splitting the cost of purchasing and installing such energy saving measures as they may mutually agree upon, but are not obligated to do so.

### 16. Landlord's Repairs, Maintenance

The Landlord shall keep, maintain and repair the Demised Premises, including without limitation, its fixtures, appurtenances, systems and facilities, sidewalks, exterior, roof, structural elements, foundation, parking lot, exterior lighting and other appurtenances thereto, in good working order and condition and will obtain and pay for maintenance service contracts for the Landlord's systems. The Landlord shall not be required to maintain or repair the Tenant's Improvements.

#### 17. Access to Demised Premises.

(a) The Landlord and the Landlord's agents shall have the right, but not the obligation, to enter and pass through the Demised Premises or any part or parts thereof during business hours and at such other times as such entry shall be required by circumstances of emergency affecting the Demised Premises (i) to examine the Demised Premises and to show them to any mortgagee, prospective mortgagees or purchasers of the Demised Premises, and (ii) for the purpose of performing such maintenance and making such repairs or changes in or to the Demised Premises or its facilities as may be provided for or permitted by this lease or as may be mutually agreed upon by the parties or as the Landlord may be required to make by laws and requirements of public authorities. The Landlord shall be allowed to take all materials into and upon the Demised Premises that may be required for such repairs, changes or maintenance. Landlord agrees to abide by Tenant's

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restricted access policies and written safety procedures. Tenant shall cooperate with Landlord in making access available consistent with such policies and procedures.

(b) During the period of six (6) months prior to the Expiration Date, the Landlord may, unless the Tenant shall have theretofore given notice to the Landlord of its election to exercise its option to renew the term of this lease, exhibit the Demised Premises to prospective tenants.

# 18. Damage or Destruction.

(a) In the event that the Demised Premises (other than Tenant's Improvements), or any part thereof, or access thereto, shall be damaged or destroyed by fire or other insured casualty, but the Tenant shall continue to have reasonably convenient access to the Demised Premises and no portion of the Demised Premises (other than Tenant's Improvements) shall thereby be rendered unfit for use and occupancy by the Tenant for the purposes set forth in Section 5, the Landlord shall promptly and diligently repair such damage or destruction (except damage or destruction to Tenant's Property or Tenant's Improvements).

During the period when such repair work is being conducted, the Rent shall not be abated or suspended.

(b) In the event that the Demised Premises (other than Tenant's Improvements), or any part thereof, or access thereto, shall be so damaged or destroyed by fire or other insured casualty that the Tenant shall not have reasonably convenient access to the Demised Premises or any portion of the Demised Premises (other than Tenant's Improvements), or so that part of but not more than 25% of the Demised Premises' square footage then in use by the Tenant shall thereby be rendered unfit for use or occupancy by the Tenant for the purposes set forth in Section 5, and if in Landlord's determination reasonably exercised the damage or destruction may be repaired within ninety (90) days after the occurrence of the damage or destruction, then the Landlord shall so notify the Tenant within thirty (30) days after the occurrence of the damage or destruction and shall promptly and diligently repair such damage or destruction (except damage or destruction to Tenant's Property or Tenant's Improvements). In the event that the Landlord shall not complete such repairs within ninety (90) days after the occurrence of the damage or destruction, then the Tenant shall have the right to terminate the term of this lease by giving written notice of such termination to the Landlord within then (10) days after the end of such ninety (90) day period. If in the Landlord's determination reasonably exercised the Demised Premises (other than Tenant's Improvements), or means of access thereto, cannot be repaired within ninety (90) days after the occurrence of the damage or destruction or, if more than 25% of the Demised Premises' square footage then in use by the Tenant should be rendered unfit for use and occupancy by Tenant, then either party shall have the right to terminate the term of this lease by giving written notice of such termination to the other party within the

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of thirty (30) to forty-five (45) days after the occurrence of such damage or destruction. If neither party give such notice of intention to terminate the term of this lease, then the Landlord shall promptly and diligently repair the damage or destruction.

- (c) If any casualty results in the suspension of business in the Demised Premises, all rents and additional charges shall abate from the date of such suspension of business until the date business is resumed. If the casualty or restoration results in a partial suspension of business, rent and additional charges shall be equitably abated during any such period. If Landlord fails to begin or complete the restoration within a reasonable time period, then Tenant may, in addition to any other remedies it may have, perform all or a portion of such restoration, and Landlord shall pay to Tenant the reasonable costs incurred by Tenant to restore the Demised Premises.
- (d) In addition to and apart from the foregoing provisions of this Section, (i) if more than twenty-five percent (25%) of the Gross Rentable Area of the Demised Premises shall be totally or almost totally damaged or destroyed by fire or other cause at any time during the last six (6) months of the term of this lease, or during the last six (6) months of any renewal or extension thereof, either the Landlord or the Tenant may terminate the term of this lease by giving written notice of such termination to the other party within ten (10) days after the occurrence of such damage or destruction, and (ii) if the building on the Demised Premises is damaged or destruction, as reasonably estimated by the Landlord, will be more than twenty-five percent (25%) of the replacement value of the building immediately prior to the occurrence of such damage or destruction, then either party may terminate the term of this lease by giving written notice of such termination to the Tenant within thirty (30) days after the occurrence of such damage or destruction.

(e) Except as provided in this Section, no damages, compensation or claim shall be payable by the Landlord to the Tenant, or any other person by reason of inconvenience, loss of business or annoyance arising from any damage or destruction, or any repair thereof, as if referred to in this Section.

#### 19. Condemnation.

(a) If all of the building, or so much of the building or the Demised Premises as is necessary for the Tenant's use and occupancy of the Demised Premises for the purposes set forth in Section 5, or for reasonably convenient access to the Demised Premises, shall be taken by condemnation or in any other manner for any public or quasi-public use and purpose, then the term of this lease shall forthwith terminate as of the date title vests in the taking authority and the Rent

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shall be apportioned as of such date.

- (b) In addition to and apart from the foregoing provisions of Section 20(a), if more than twenty-five percent (25%) of the Gross Rentable Area of the building shall be so taken, then either party may terminate the term of this lease by giving written notice of such termination to the other within thirty (30) days after the date title vests in the taking authority.
- (c) The Tenant shall have the exclusive right in any proceeding with respect to any taking referred to in this Section 20 to any award payable for the Tenant's moving expenses and the then value of the Tenant's Property, but the Tenant shall have no other right to any award for either a total taking or a partial taking of the land, the building or the Demised Premises, including any right for the contract value of this lease, and any such award shall be retained by the Landlord as the Landlord's sole property.
- (d) In the event of any taking which does not result in a termination of the term of this lease, the Rent shall be equitably suspended or abated and the Landlord, at its expense, shall proceed with reasonable diligence to repair and restore the remaining part of the building and the Demised Premises to substantially its former condition to the extent that the same may be feasible. Any suspension or abatement of Rent shall cease upon substantial completion of such repairs or restoration.
- 20. Surrender. On the Expiration Date, or on the expiration of the final renewal period to which the Tenant exercises its right, or upon any earlier termination of the term of this lease, the Tenant shall quit and surrender the Demised Premises, including Tenant's Improvements, to the Landlord in good order, condition and repair, except for (a) Ordinary wear and tear and (b) Conditions requiring repairs which are not required to be made by the Tenant. The Tenant shall remove all of the Tenant's Property, and at the Landlord's request, shall remove those portions of the Tenant's Improvements as shall be designated by the Landlord for Tenant's removal at the time the Landlord approves the plans therefor, and shall repair any damage to the Demised Premises on account of such removal.

## 21. Default and Damages.

(a) Any of the following occurrences or acts shall constitute an event of default under this lease: (i) whenever the Tenant shall default in the payment of any Rent or any other charge payable by the Tenant to the Landlord, on any day upon which the same is due, and such default shall continue for five (5) days after written notice thereof from Landlord; or (ii) whenever the

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Tenant shall do, or fail to do, or permit to be done, whether by action or inaction, anything contrary to any of the Tenant's obligations hereunder, and if such situation shall continue and shall not be remedied by the Tenant within

- (A) Five (5) days after notice in the case of any voluntary situation within the Tenant's reasonable control, or
- (B) Thirty (30) days in the case of any involuntary situation not within the Tenant's reasonable control, after the Landlord shall have given to the Tenant a notice specifying the same, or, in the case of a situation which cannot with due diligence be cured within a period of five (5) or thirty (30) days, as the case may be, if the Tenant shall not (1) within such 5-day or 30-day period, as the case may be, advise the Landlord of the Tenant's intention duly to institute all steps necessary to remedy such situation, and (2) duly institute within such 5-day or 30-day period, as the case may be, and thereafter diligently prosecute to completion, all steps necessary to remedy the same; (iii) whenever the Tenant is dissolved (other than in the contest of a corporate reorganization where the business enterprise is continued), makes assignment for the benefit of creditors, files a voluntary petition in bankruptcy, is adjudicated a bankrupt or insolvent, files a petition or answer seeking for the Tenant any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any statute, law or regulation, files an answer or other pleading admitting or failing to contest material allegations of a petition filed against the Tenant in any proceeding of this nature, or seeks, consents to, or acquiesces in the appointment of a trustee, receiver, or liquidator of the Tenant or of all or any substantial part of the Tenant's properties; or (iv) if within sixty (60) days after the commencement of any proceeding against the Tenant seeking reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any statute, law, or regulation, the proceeding has not been dismissed; or if within sixty (60) days after the appointment without the Tenant's consent or acquiescence of a trustee, receiver, or liquidator of the Tenant or of all or any substantial part of the Tenant's properties, the appointment is not vacated or stayed; or if within sixty (60) days after expiration of any such stay, the appointment is not vacated; or (v) the event of an occurrence of default beyond any applicable grace period in that certain \$87,000 Promissory Note from Tenant to Landlord of even date herewith.
- (b) If an event of default shall have happened and be continuing, the Landlord shall have the immediate right at its election (i) to terminate the term of this lease by giving the Tenant not less than five (5) days written notice of the Landlord's election to terminate, and (ii) whether or not the Landlord shall have terminated the term of this lease pursuant to this Section 21(b), and without demand or notice whatever, to re-enter and take possession of the Demised Premises, removing all persons and property therefrom either by summary process proceedings or by other action, without being liable for any damages therefor.

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- (c) If the Landlord elects to re-enter and take possession of the Demised Premises pursuant to Section 21 (b), and whether or not the Landlord shall have terminated the term of this lease pursuant to Section 21 (b), the Landlord may (but shall be under no obligation to) re-let the whole or any part of the Demised Premises on behalf of the Tenant for a period equal to, or greater or less than, the remainder of the term of this lease, at such rent and upon such terms and conditions as the Landlord shall determine reasonable, to any tenant the Landlord may consider suitable and for any use or purpose the Landlord may deem appropriate in the Demised Premises. The Landlord shall not be liable for failure to re-let the Demised Premises, and the Landlord shall be entitled to receive and retain the rent received upon such re-letting, whether or not such rent is in excess of the Rent.
- (d) Should Landlord elect to re-enter as herein provided or should it take possession pursuant to legal proceedings or pursuant to any notice provided for by law, it may either terminate this Lease or make such alterations and repairs as may be necessary in order to relet the premises, and relet said premises or any part thereof for such term or terms (which may be for a term extending beyond the term of this Lease) and at such rental or rentals and upon such other terms and conditions as Landlord in its discretion may deem advisable; and upon each such reletting all rentals received by the Landlord from such reletting shall be applied first, to the payment of any indebtedness other than rent due hereunder from Tenant to Landlord; second, to the payment of any costs and expenses of such reletting, including brokerage fees and attorneys' fees and of costs and expenses of such reletting, including the costs of recovering possession of the Demised Premises, brokerage fees and attorneys' fees and of costs of such alterations and repairs; third, all utility expenses and expenses of maintaining the Demised Premises while vacant, fourth, to the payment of rent due and unpaid hereunder, and the residue, if any, shall be held by Landlord and applied in payment of future rent as the same may become due and payable hereunder. If such rentals received from such reletting during any month be less than that to be paid during that month by Tenant hereunder, Tenant shall pay any deficiency to Landlord. Such deficiency shall be calculated and paid monthly. No such re-entry or taking possession of Demised Premises by Landlord shall be construed as an election on its part to terminate this Lease unless a written notice of such intention be given to Tenant or unless the termination thereof be decreed by a court of competent jurisdiction.
- 22. Parking. The Landlord shall provide to the Tenant seventy (70) parking spaces in the parking area provided and maintained by the Landlord.
- 23. Unperformed Covenants. If the Tenant shall default in the performance of any of the Tenant's obligations hereunder, the Landlord, without thereby waiving such default, may, at the Landlord's option, by reason of any default of the Tenant hereunder, perform the same for the

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account of the Tenant. If the Landlord makes any expenditures or incurs any obligations for the payment of money, including attorneys' fees, such sums paid or obligations incurred shall be paid by the Tenant to the Landlord on the first day of the calendar month next following the rendition to the Tenant of the Landlord's bill therefor to the Tenant.

24. Holding Over. The Tenant shall pay to the Landlord an amount as Rent equal to one hundred fifty percent (150%) of one-twelfth (1/12) of the Fixed Rent required to be paid by the Tenant during the previous Lease Year as herein provided for each month or portion thereof for which the Tenant shall retain possession of the Demised Premises, or any part thereof, after the termination of the term of this lease, whether by lapse of time or otherwise, and also shall pay all damages sustained by the Landlord, whether direct or consequential, on account thereof. The provisions of this Section 24 shall not

be deemed to limit or constitute a waiver of any other rights or remedies of the Landlord provided herein or at law. Without limiting any rights or remedies of the Landlord resulting by reason of the wrongful holding over by the Tenant, or creating any right in the Tenant to continue in possession of the Demised Premises, all of the Tenant's obligations with respect to the use, occupancy and maintenance of the Demised Premises shall continue during such period of unlawful retention.

- 25. Certain Rights Reserved by the Landlord. The Landlord shall have the following rights, each of which the Landlord may exercise with notice to the Tenant but without liability to the Tenant for damage or injury to property, person or business on account of the exercise thereof, and the exercise of any such rights shall not be deemed to constitute an eviction or disturbance of the Tenant's use or possession of the Demised Premises and shall not give rise to any claim for set-off or abatement of rent or any other claim, provided that the Landlord agrees that in the exercise of such rights it shall not do or cause to be done anything which is, in any material respect, inconsistent with the operation of the Demised Premises as a first-class/laboratory office building:
- (a) To change the building's street address, if required by the U.S. Postal Service
- (b) To install, affix and maintain any and all reasonable directional signs on the land of the Demised Premises.
- (c) Upon reasonable notice to Tenant, to make repairs, or improvements, whether structural or otherwise, in an about the building, or any part thereof, and for such purposes to enter upon the Demised Premises, Landlord agrees to use reasonable efforts to cause minimal disruption to the Tenant's use of the Demised Premises.

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- (d) The Tenant shall not install or operate machinery or any mechanical devices of a nature not directly related to the Tenant's ordinary use of the Demised Premises without the prior written consent of the Landlord. The Tenant's movements of property into or out of the building or Demised Premises and within the building are entirely at the risk and responsibility of the Tenant.
- 26. Waiver of Notice. The Tenant hereby waives any notice to quit under the statutes relating to summary process which, were it not for this waiver, might otherwise be necessary in obtaining possession of the Demised Premises.
- 27. Notices. Any notice, approval, request, consent, bill, statement or other communication required or permitted to be given, rendered, served or made by either party hereto, shall be in writing and shall be sent by certified or registered United Stated Mail, postage prepaid, return receipt requested, or federal express, or hand delivery or over night carrier:
  - (a) addressed to the Tenant at:

BBI - North American Clinical Laboratories, Inc. C/O Boston Biomedica, Inc. 375 West Street
West Bridgewater, MA 02379
Attn: Treasurer
Fax No. 508-580-1110
Telephone No. 508-580-1900

(b) addressed to the Landlord at:

MB Associates 414 New Britain Road P.O. Box 99 Plainville, CT 06062

Attn: Property Management Department

Fax No. 203-747-5299 Telephone No. 203-229-4853

Either party may, from time to time, by written notice to the other, designate a different mailing address for notices, bills, statements or other communications intended for it.

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- 28. Estoppel Certificate. The Tenant shall, from time to time, within ten (10) days after the Landlord's written request, deliver to the Landlord a written certificate, in recordable form, ratifying this lease, and stating
  - (a) the Commencement Date and the Expiration Date,
- (b) that this lease is in full force and effect and has not been assigned, modified, supplemented or amended (except by such writings as shall be stated),
- (c) that all conditions under this lease to be performed by the Landlord have been satisfied,
- (d) that there are no defenses or offsets against the enforcement of this lease by the Landlord, or stating those claimed by the Tenant,
- (e) the amount of advance rental, if any (or none if such is the case), paid by the Tenant,
  - (f) the date to which rental has been paid, and
- (g) the amount of security deposited with the Landlord, provided, however, that the Tenant shall not be required to make written declarations as to any matters which to its knowledge are inaccurate or not true. Any such certificate may be relied upon by any mortgagee of the Land and the building, any assignee of such mortgagee, and any prospective purchaser of the Land and the building. Landlord agrees to provide written confirmation of the Lease terms and status upon Tenant's written request.
- 29. Limitation of Liability. Anything in this lease to the contrary notwithstanding, the Tenant agrees that it shall look solely to the estate and property of the Landlord in the Demised Premises for the collection of any judgment (or other judicial process) requiring the payment of money by the Landlord in the event of any default or breach by the Landlord with respect to any of the terms, covenants and conditions of this lease to be observed or performed by the Landlord, and no other assets of the Landlord or of any partner in the Landlord shall be subject to levy, execution or other procedures for the satisfaction of the Tenant's remedies.
- 30. Rights of Landlord; Non-Waiver. No right or remedy herein conferred upon or reserved to the Landlord is intended to be exclusive of any other right or remedy, and every right and remedy shall be cumulative and in addition to any other right or remedy given hereunder or now or

 (Landlord)
(Tenant)

hereafter existing. The failure of the Landlord to insist upon the strict performance of any provision hereof or to exercise any option, right, power or remedy contained herein shall not be construed as a waiver or relinquishment thereof for the future. Receipt by the Landlord of any Fixed Rent, any additional rent or any other sum payable hereunder with knowledge of the breach of any provision hereof shall not be deemed a waiver of such breach, and no waiver by the Landlord of any provision hereof shall be deemed to have been made unless expressed in writing and signed by the Landlord. In addition to other remedies provided herein, the Landlord shall be entitled, to the extent not prohibited by law, to injunctive relief in case of the violation, or attempted or threatened violation, of any of the provisions hereof, or to a decree compelling performance of any of the provisions hereof, or to any other remedy allowed to the Landlord by law.

31. Broker. The Tenant represents that no broker or agent other than Grubb & Ellis participated with the Tenant in this transaction. The Tenant agrees to indemnify and hold the Landlord harmless from and against any claim or demand of any other broker or agent who claims that he participated with the Tenant in this transaction. Landlord represents that it has only dealt with Grubb & Ellis in connection with this lease.

#### 32. Notice of Lease.

- (a) This lease shall not be recorded in the New Britain Land Records. Upon the request of either party, the other party shall execute a Notice of Lease, in recordable form, satisfying the requirements of Section 47-19 of the Connecticut General Statutes, Rev. 1958, as amended.
- (b) The parties shall also enter into recordable supplementary notices setting forth, among other proper matters, such items as the termination of this lease and the exercise of any options afforded by this lease.
- 33. Prior Agreements. This lease and the exhibits and Notice of Lease constitute the entire agreement by and between the parties hereto affecting the Demised Premises and supersedes any and all previous agreements, written or oral, between the parties and affecting the Demised Premises.
- 34. Captions; Sections; Gender. The captions contained herein have been inserted for convenience only and shall not have the effect of modifying, amending or changing the express terms and provisions of this lease. All references to a "Section" shall refer to a Section of this lease unless the context otherwise requires. Whenever used, the singular number shall include the plural, the plural the singular, and use of any gender shall include all genders.

Initials	
	(Landlord)
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- 36. Applicable Law. This Lease shall be governed by and construed in accordance with the laws of the State of Connecticut.
- 37. Signatures. This Lease may be signed in counterparts and any number of counterparts signed in the aggregate by the parties shall constitute a single original document. Additionally, a facsimile signature shall be deemed equivalent to an original signature.

TENANT ACKNOWLEDGES THAT THIS LEASE IS A COMMERCIAL TRANSACTION AND THAT IT HAS THE RIGHT UNDER CHAPTER 903a of the CONNECTICUT GENERAL STATUTES, SUBJECT TO CERTAIN LIMITATIONS, TO NOTICE OF, AND HEARING ON, THE RIGHT OF THE LANDLORD TO OBTAIN A PREJUDGMENT REMEDY, SUCH AS ATTACHMENT OR GARNISHMENT UPON COMMENCING ANY LITIGATION AGAINST IT. NOTWITHSTANDING, TENANT HEREBY WAIVES ALL RIGHTS TO NOTICE, JUDICIAL HEARING OR PRIOR COURT ORDER IN CONNECTION WITH THE ASSERTION BY THE LANDLORD OF ANY PREJUDGMENT REMEDY TO COLLECT THE OBLIGATIONS OR TO ENFORCE LANDLORDS RIGHTS HEREUNDER.

IN WITNESS WHEREOF, the Landlord and the Tenant have hereunto caused to be set their hands and seals as of the day and year first above written.  WITNESSES:  LANDLORD: MB ASSOCIATES  By  A Partner, Duly Authorized  TENANT: BBI - NORTH AMERICAN CLINICAL LABORATORIES, INC.  By  Kevin Quinlan Its Sr. Vice President & Treasurer Duly Authorized
be set their hands and seals as of the day and year first above written.  WITNESSES:  LANDLORD: MB ASSOCIATES  By  A Partner, Duly Authorized  TENANT: BBI - NORTH  AMERICAN CLINICAL LABORATORIES, INC.  By  Kevin Quinlan Its Sr. Vice President & Treasurer
ByA Partner, Duly Authorized  TENANT: BBI - NORTH AMERICAN CLINICAL LABORATORIES, INC.  By Kevin Quinlan Its Sr. Vice President & Treasurer
A Partner, Duly Authorized  TENANT: BBI - NORTH AMERICAN CLINICAL LABORATORIES, INC.  By  Kevin Quinlan Its Sr. Vice President & Treasurer
TENANT: BBI - NORTH AMERICAN CLINICAL LABORATORIES, INC.  By  Kevin Quinlan Its Sr. Vice President & Treasurer
AMERICAN CLINICAL LABORATORIES, INC.  By  Kevin Quinlan Its Sr. Vice President & Treasurer
Kevin Quinlan Its Sr. Vice President & Treasurer
Its Sr. Vice President & Treasurer
Initials(Landlord)(Tenant)
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STATE OF CONNECTICUT) ) ss: July 28, 1995 COUNTY OF HARTFORD)  Personally appeared, of MB Associates, signer and sealer of the foregoing instrument and acknowledged the

	Comm	nissioner, Superior Court	
	Notary	/ Public	
	My Co	ommission Expires:	
STATE OF	)		
	) ss:	July 28, 1995	
COUNTY OF	)		
Personally a	nneared		of BBI -
•		es, Inc., signer and sealer of	
		ame to be his free act and o	~ ~
	id corporation, before		iced and the free
act and acca of sa	ia corporation, ocic	ne me.	
	Comm	nissioner, Superior Court	
	Notary	Public	
	My Co	ommission Expires:	

same to be his free act and deed and the free act and deed of said partnership,

before me.

# GUARANTY OF TENANT'S PERFORMANCE

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In consideration of Landlord's having executed said Lease a the request of the undersigned and in further consideration of One Dollar (\$1.00) and other valuable considerations paid, the receipt whereof is hereby acknowledged, the undersigned (Guarantor) hereby unconditionally guarantees to Landlord and its successors and assigns, the payment of the rents and other sums provided for in said Lease and the performance and observance of all agreements and conditions contained in said Lease on the part of Tenant to be performed or observed.

Guarantor hereby waives presentment for payment, demand for payment, notice of nonpayment or dishonor, protest and notice of protest, diligence in collection, and any and all

Initials	
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	(Tenant)

formalities which may be legally required to charge it with liability; and the Guarantor does further agree that its liability as Guarantor shall in nowise be impaired or affected by any renewals, waivers, or extensions which may be made from time to time, with or without its knowledge and consent, of any default or the time of payment or performance required under said Lease, or by any forbearance or delay in enforcing any obligation thereof, or by assignment of said Lease or subletting of the demised premises, neglect or refusal to enforce or to realize upon any security which may have been given or may hereafter be given thereunder or hereunder, or by any modifications of the terms or provisions of the Lease.

The Guarantor further covenants and agrees to pay all expenses and fees, including attorney's fees which may be incurred by the landlord or its successors and assigns in enforcing any of the terms or provisions of this Guaranty.

This Guaranty shall be binding upon the successors, and assigns of the Guarantors, shall not be discharged or affected, in whole or in part by the bankruptcy, or insolvency of the Tenant.

This Guaranty is absolute, unconditional, and continuing and payment of

the sums for which the undersigned become liable shall be made at the office of the Landlord or its successors or assigns from time to time on demand as the same become or are declared due.

Dated: July 28, 1995	BOSTON BIOMEDICA, INC.
BY:	
Ke	vin Quinlan
	Sr. Vice President & Treasurer
Du	ly Authorized
	Initials
	(Landlord)
	(Tenant)
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EXHIBIT	ГА
EARIBIT	1 A
LEASED F	PREMISES
EVIDIT	141
EXHIBIT	A
LEASED P.	REMISES

A certain piece or parcel of land with all buildings and improvements thereon situated northerly of North Mountain Road in the City of New Britain, Connecticut and being more particularly shown on a map entitled "Map Showing Location Of Proposed Leasing Agreement For BBI - North American Clinical Laboratories, Inc. Located At #75 North Mountain Road, New Britain, Connecticut Map Prepared By: MBA Engineering, Inc., 211 New Britain Road, Suite 103, Kensington, Connecticut 06037 (203) 827-0222 Job Number: 95068, Scale 1" = 50' Drawn By: BNB Checked By LJM Date: July 13, 1995" and containing 4.081 +/- acres and being more particularly bounded and described as follows:

Beginning at a point located in the westerly line of Lot No. 206 which point is the southeast corner of the within described premises; thence running N 890 07' 53" W. 417.53 feet to a point as shown on said map; thence running N 060 75' 26" E, 66.77 feet to a point as shown on said map; thence running N 310 03' 55" W, 35.15 feet to a point as shown on said map; thence running N 000 09' 15" W. 276.41 feet, to a point as shown on said map; thence running N 770 44' 24" E, 291.54 feet, to a point as shown on said map; thence running S 860 44' 06" E, 152.84 feet to a point as shown on said map; thence running S O10 07' 17" W. 426.62 feet to the point and place of beginning.

Said premises are leased together with a 30 foot wide right-of-way from North Mountain Road to the leased premises, in common with the Landlord and others, for motor vehicle and pedestrian ingress and egress. Said right-of-way is shown on said map as "Minimum 30 Ft. Wide Driveway Right-of-Way From North Mountain Road to Leased Portion of Site. R.O.W. to be centered of 24 Ft. BIT. Driveway" and "Minimum 30 Ft. Wide Right-of-Way From Driveway R.O.W. To Front Entrance of Site. R.O.W. to be centered over aisle portion of existing BIT. Parking Lot."

Initials	
	(Landlord)
	(Tenant)

## EXHIBIT B

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#### SCHEDULE OF LANDLORD'S WORK

The Improvement list below is a detailed list subject to minor modifications. These "modifications" must be finalized immediately. Both parties understand that this final plan directly correlates to the Landlord's Performance Schedule.

#### Improvements

- 1. Existing cafeteria to be subdivided and used as an employee lounge and soundproofed conference room.
- 2. One existing Lab area, as specified in the front left area of the facility, to be renovated into 3 or 4 offices, to be located as reasonably determined by Tenant.
- 3. One existing lab area to be refurbished as a client service/specimen processing, as determined by Tenant.
- 4. all existing computer and phone wiring to be removed.
- 5. Floor areas, as designated by Tenant, to be sealed.
- 6. All carpets, as designated by Tenant, to be replaced.
- 7. Any damaged ceiling tiles to be replaced.
- 8. Interior to be cleaned and painted.
- 9. Landlord to warrant that electrical systems HVAC and plumbing are in good working order, including all Emergency Lighting, exterior building/parking lot lighting and the existing security camera in the parking area is operational.
- 10. New driveway and parking area adjacent to Tenant's building.
- 11. Lab furniture to be in good working order as reasonably determined by the parties.

Initials	
	(Landlord)
	(Tenant)

12. Landlord to warrant that the electric circuits are fully operational via the back-up generator or will identify which circuits/outlets are operational from this generator.

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	(Landlord)
	(Tenant)

EXHIBIT C

- 1. The sidewalks, entrances, passages, courts, elevators, vestibules, stairways, corridors and public parts of the Building shall not be obstructed or encumbered by Tenant or used by Tenant for any purpose other than ingress and egress to and from the Demised Premises.
- 2. No awnings, air conditioning units or other projections shall be attached to the outside walls or windowsills of the Building or otherwise project from the Building, without the prior written consent of landlord.
- 3. All signs or lettering affixed by Tenant on any part of the outside of the Demised Premises shall be approved by landlord, which approval shall not be unreasonably withheld or delayed.
- 4. No bottles, parcels or other articles be placed on the windowsills or in any other part of the Building, nor shall any article be thrown out of the doors or windows of the Demised Premises.
- 5. Tenant shall not make, or permit to be made, unseemly or disturbing noises or interfere with other tenants or those having business with them.
- 6. Tenant shall not put any covering of any type or nature upon the exterior of windows in the Demised Premises.

Initials	
	(Landlord)
	(Tenant)

### EXHIBIT 23.2

### CONSENT OF INDEPENDENT ACCOUNTANTS

We consent to the inclusion in this Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-10759) of our reports dated March 12, 1996, except as to the information in the first paragraph of Note 11, for which the date is September 10, 1996 on our audits of the financial statements and financial statement schedule of Boston Biomedica, Inc. and Subsidiaries. We also consent to the references to our firm under the captions "Selected Consolidated Financial Data" and "Experts."

COOPERS & LYBRAND L.L.P.

Boston, Massachusetts October 25, 1996