UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2004

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 0-15006

AVANT IMMUNOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

No. 13-3191702

(State of Incorporation)

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

119 Fourth Avenue, Needham, Massachusetts 02494-2725

(Address of principal executive offices) (Zip Code)

(781) 433-0771

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes No o.

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

As of November 3, 2004, 74,129,400 shares of common stock, \$.001 par value per share, were outstanding.

AVANT IMMUNOTHERAPEUTICS, INC.

FORM 10-Q Quarter Ended September 30, 2004 Table of Contents

Part I — Financial Information

Unaudited, Consolidated Balance Sheet at September 30, 2004 and December 31, 2003

Unaudited, Consolidated Statement of Operations for the Three Months Ended September 30, 2004 and 2003

Unaudited, Consolidated Statement of Operations for the Nine Months Ended September 30, 2004 and 2003

Unaudited, Consolidated Statement of Cash Flows for the Nine Months Ended September 30, 2004 and 2003

Notes to Unaudited, Consolidated Financial Statements

Management's Discussion and Analysis of Financial Condition and Results of Operations

Quantitative and Qualitative Disclosures about Market Risk

Controls and Procedures

Part II — Other Information

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

AVANT IMMUNOTHERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEET September 30, 2004 and December 31, 2003 (Unaudited)

| (Unautiteu) | | |
|---|-----------------------|----------------------|
| | September 30, 2004 | December 31, 2003 |
| ASSETS | | |
| Current Assets: | | |
| Cash and Cash Equivalents | \$ 35,228,300 | \$ 20,251,000 |
| Accounts Receivable | 615,800 | 1,472,800 |
| Prepaid Expenses and Other Current Assets | 770,700 | 585,200 |
| Total Current Assets | 36,614,800 | 22,309,000 |
| Property and Equipment, Net | 2,171,700 | 912,700 |
| Intangible and Other Assets | 6,311,000 | 7,047,100 |
| Goodwill | 1,036,300 | 1,036,300 |
| Total Assets | \$ 46,133,800 | \$ 31,305,100 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts Payable | \$ 650,400 | \$ 475,800 |
| Accrued Expenses | 3,028,800 | 1,453,400 |
| Deferred Revenue | 132,900 | 1,456,200 |
| Total Current Liabilities | 3,812,100 | 3,385,400 |
| Note Payable | 342,700 | _ |
| Stockholders' Equity: | | |
| Convertible Preferred Stock, 4,513,102 Shares Authorized; None Issued and Outstanding at September 30, 2004 and December 31, 2003 | | |
| Common Stock, \$.001 Par Value; 100,000,000 Shares Authorized; 74,347,200 Issued and 74,126,900Outstanding at September 30, 2004 and 64,928,400Issued and 64,708,100 Outstanding at | _ | _ |
| December 31, 2003 | 74,300 | 64,900 |
| Additional Paid-In Capital | 256,991,800 | 233,643,500 |
| Deferred Compensation | (782,000) | (989,000) |
| Less: 220,300 Common Treasury Shares at Cost at September 30, 2004 and December 31, 2003 | (227,600) | (227,600) |
| Accumulated Deficit | (214,077,500) | (204,572,100) |
| Total Stockholders' Equity | 41,979,000 | 27,919,700 |
| Total Liabilities and Stockholders' Equity | \$ 46,113,800 | \$ 31,305,100 |

See accompanying notes to unaudited consolidated financial statements

3

AVANT IMMUNOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENT OF OPERATIONS

For the Three Months Ended September 30, 2004 and 2003 (Unaudited)

September 30, September 30, 2004 2003

| REVENUE: | | | | |
|--|--------------|--|----|-------------|
| Product Development and Licensing Agreements | \$ | 144,300 | \$ | 1,232,900 |
| Government Contracts and Grants | | 334,200 | | 733,700 |
| Product Royalties | | 49,100 | | 48,500 |
| | | | | |
| Total Revenue | | 527,600 | | 2,015,100 |
| | | | | |
| OPERATING EXPENSE: | | | | |
| Research and Development | | 2,805,800 | | 2,510,100 |
| General and Administrative | | 1,290,600 | | 1,423,700 |
| Amortization of Acquired Intangible Assets | | 248,800 | | 248,800 |
| | _ | <u>, </u> | | <u> </u> |
| Total Operating Expense | | 4,345,200 | | 4,182,600 |
| | | | | |
| Operating Loss | | (3,817,600) | | (2,167,500) |
| -F 0 | | (-,- ,, | | (, - , , |
| Investment and Other Income, Net | | 120,400 | | 51,800 |
| | | | | |
| Net Loss | \$ | (3,697,200) | \$ | (2,115,700) |
| 110. 2000 | - | (=,== , ==) | ÷ | (, 1, 11) |
| Basic and Diluted Net Loss Per Common Share | \$ | (0.05) | \$ | (0.03) |
| Dasic and Diracca Net Loss I et Common Share | Ψ | (0.03) | Ψ | (0.03) |
| Waighted Average Common Charge Outstanding | | 74,118,300 | | 64,703,000 |
| Weighted Average Common Shares Outstanding | | /4,110,300 | | 04,703,000 |

See accompanying notes to unaudited consolidated financial statements

4

AVANT IMMUNOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENT OF OPERATIONS

For the Nine Months Ended September 30, 2004 and 2003 (Unaudited)

| | September 30, | | | September 30, 2003 |
|--|-------------------|-------------|----|-----------------------|
| REVENUE: | | | | |
| Product Development and Licensing Agreements | \$ | 2,393,100 | \$ | 1,620,000 |
| Government Contracts and Grants | | 1,928,800 | | 2,029,300 |
| Product Royalties | | 129,400 | | 125,900 |
| Total Revenue | | 4,451,300 | | 3,775,200 |
| OPERATING EXPENSE: | | | | |
| Research and Development | | 9,626,800 | | 7,876,000 |
| General and Administrative | | 3,852,400 | | 4,000,100 |
| Amortization of Acquired Intangible Assets | | 746,400 | | 746,400 |
| Total Operating Expense | | 14,225,600 | | 12,622,500 |
| Operating Loss | | (9,774,300) | | (8,847,300) |
| Investment and Other Income, Net | | 268,900 | | 186,100 |
| Net Loss | \$ | (9,505,400) | \$ | (8,661,200) |
| Basic and Diluted Net Loss Per Common Share | \$ | (0.13) | \$ | (0.14) |
| Weighted Average Common Shares Outstanding | | 72,510,600 | | 61,773,500 |

 $See\ accompanying\ notes\ to\ unaudited\ consolidated\ financial\ statements$

5

AVANT IMMUNOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENT OF CASH FLOWS

(Unaudited)

| | September 30, 2004 | | | eptember 30, 2003 |
|---|-----------------------|-------------|----|----------------------|
| Cash Flows from Operating Activities: | | | | |
| Net Loss | \$ | (9,505,400) | \$ | (8,661,200) |
| Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities: | | | | |
| Depreciation and Amortization | | 1,045,200 | | 1,293,800 |
| Amortization of Deferred Compensation | | 207,000 | | 46,000 |
| Changes in Operating Assets and Liabilities: | | | | |
| Accounts Receivable | | 1,199,700 | | (337,600) |
| Prepaid and Other Current Assets | | (185,500) | | (156,500) |
| Accounts Payable and Accrued Expenses | | 1,750,000 | | (279,600) |
| Deferred Revenue | | (1,323,300) | | (360,800) |
| Net Cash Used in Operating Activities | | (6,812,300) | | (8,455,900) |
| Cash Flows from Investing Activities: | | | | |
| Acquisition of Property and Equipment | | (1,557,800) | | (167,800) |
| Increase in Patents | | (1,557,000) | | (142,800) |
| Cash Paid for Acquisition of Universal Preservation Technologies, Inc. Assets | | 3/4 | | (2,000,000) |
| Other Non-Current Assets | | (10,300) | | 34 |
| Cash Used in Investing Activities | _ | (1,568,100) | | (2,310,600) |
| Cash Flows from Financing Activities: | | | | |
| Proceeds from Stock Issuance | | 23,051,000 | | 9,274,600 |
| Proceeds from Exercise of Stock Options and Warrants | | 306,700 | | 10,900 |
| Purchases of Treasury Stock | _ | 3/4 | | (91,300) |
| Net Cash Provided by Financing Activities | | 23,357,700 | | 9,194,200 |
| Net Increase (Decrease) in Cash and Cash Equivalents | | 14,977,300 | | (1,572,300) |
| Cash and Cash Equivalents at Beginning of Period | | 20,251,000 | | 25,070,700 |
| Cash and Cash Equivalents at End of Period | \$ | 35,228,300 | \$ | 23,498,400 |
| Supplemental Disclosure of Noncash Financing Activities | | | | |
| Note payable from MassDevelopment | | 342,700 | | 3⁄4 |

Supplemental Disclosure of Cash Flow Information See Note 7.

See accompanying notes to unaudited consolidated financial statements

(

AVANT IMMUNOTHERAPEUTICS, INC. Notes to Consolidated Financial Statements September 30, 2004

(1) Nature of Business

AVANT Immunotherapeutics, Inc. is engaged in the discovery, development and commercialization of products that harness the human immune system to prevent and treat disease. The Company is developing a broad portfolio of vaccines and therapeutics against cardiovascular, viral and bacterial diseases. These include a treatment to reduce complement-mediated tissue damage associated with cardiac by-pass surgery, single-dose oral vaccines aimed at protecting travelers and people in endemic regions from infectious diseases and a proprietary vaccine candidate for cholesterol management. In addition, the Company is developing the VitriLifeÒ preservation technology for use in AVANT's oral vaccines and certain other non-injectable applications. VitriLife® is a patented drying method for the industrial-scale preservation of biological solutions and suspensions, such as proteins, enzymes, viruses, bacteria and other cells, which has the potential to cut production costs and improve product stability at room temperature or higher. AVANT further leverages the value of its technology portfolio through corporate partnerships. Current collaborations encompass the development of an oral human rotavirus vaccine, vaccines to combat threats of biological warfare, and vaccines addressed to human food safety and animal health.

The unaudited consolidated financial statements include the accounts of AVANT Immunotherapeutics, Inc. and its wholly owned subsidiary, Megan Health, Inc. All intercompany transactions have been eliminated.

(2) <u>Interim Financial Statements</u>

The accompanying unaudited consolidated financial statements for the three months and nine months ended September 30, 2004 and 2003 include the consolidated accounts of AVANT, and have been prepared in accordance with instructions to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, the information contained herein reflects all adjustments, consisting solely of normal recurring adjustments, that are necessary to present

fairly the Company's financial position at September 30, 2004, results of operations for the three-and nine-month periods ended September 30, 2004 and 2003, and cash flows for the nine-month periods ended September 30, 2004 and 2003. The results of operations for the three- and nine-month periods ended September 30, 2004 are not necessarily indicative of results for any future interim period or for the full year.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted, although we believe that the disclosures included, when read in conjunction with AVANT's Annual Report on Form 10-K for the year ended December 31, 2003, are adequate to make the information presented not misleading.

(3) Recent Accounting Pronouncements

In April 2004, the EITF reached consensus on EITF Issue No. 03-6, "Participating Securities and the Two Class Method under FASB Statement No. 128" ("EITF 03-6"). EITF 03-6 addresses a number of questions regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. EITF 03-6 also provides further guidance in applying the two-class method of calculating earnings per share, clarifying what constitutes a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-6 was effective for fiscal periods beginning after March 31, 2004 and requires retroactive restatement of prior earnings per share amounts. The adoption of this standard did not have an impact on

7

either AVANT's operating results or financial position as the Company incurred a net loss for the three and nine month periods ended September 30, 2004 and 2003. This pronouncement will have an impact when the Company incurs a net income and at that time, AVANT will evaluate whether our existing securities meet the definitions of a "participating security" under the provisions of EITF 03-6.

The Accounting Standards Executive Committee (AcSEC) Statement of Position (SOP) 01-6, "Accounting by Certain Entities (Including Entities With Trade Receivables) That Lend to or Finance the Activities of Others", includes guidance applicable to all entities with respect to recognition and measurement as well as presentation and disclosure of trade receivables. Included in its scope are nonfinancial entities that extend trade credit to customers. The following disclosure is required:

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company has not historically experienced credit losses from its trade accounts receivable and therefore has not established an allowance for doubtful accounts. The Company does not have any off-balance-sheet credit exposure related to its customers.

Accounts receivable consists of the following:

| | Sep | otember 30, 2004 | December 31, 2003 |
|-------------------|-----|---------------------|--------------------------|
| Trade Receivables | \$ | 273,100 | \$ 1,457,300 |
| Other Receivables | | 342,700 | 15,500 |
| | \$ | 615,800 | \$ 1,472,800 |

Other receivables at September 30, 2004 represents disbursement increments due from Mass Development under a Lease Agreement discussed in Footnote 10.

(4) Property and Equipment

Property and equipment includes the following:

| | _ | September 30, 2004 | December 31, 2003 |
|--|----|-----------------------|--------------------------|
| Laboratory Equipment | \$ | 2,466,000 | \$ 2,422,100 |
| Manufacturing Equipment | | 6,700 | 3⁄4 |
| Office Furniture and Equipment | | 1,684,400 | 1,633,500 |
| Leasehold Improvements | | 1,699,700 | 1,668,400 |
| Construction in Progress | | 1,425,000 | 3/4 |
| Property and Equipment, Total | | 7,281,800 | 5,724,000 |
| Less Accumulated Depreciation and Amortization | | (5,110,100) | (4,811,300) |
| | \$ | 2,171,700 | \$ 912,700 |

(5) <u>Intangible and Other Assets</u>

Intangible and other assets include the following:

| | | September | 30, 2004 | December 31, 2003 | | | | | |
|-----------------------------|--------------------|-------------------------------|-----------------------------|-----------------------------|-------------------------------|-----------------------------|-----------------------------|--|--|
| | Estimated Lives | Gross Intangible Assets | Accumulated Amortization | Net Intangible Assets | Gross Intangible Assets | Accumulated Amortization | Net Intangible Assets | | |
| Intangible Assets: | | | | | | | | | |
| Collaborative Relationships | 5 years | 1,090,000 | (1,090,000) | 3/4 | 1,090,000 | (1,090,000) | 3/4 | | |
| Core Technology | 10 years | 3,786,900 | (1,035,000) | 2,751,900 | 3,786,900 | (751,000) | 3,035,900 | | |
| Developed Technology | 7 years | 3,263,100 | (1,784,800) | 1,478,300 | 3,263,100 | (1,435,600) | 1,827,500 | | |
| Strategic Partner Agreement | 17 years | 2,563,900 | (578,100) | 1,985,800 | 2,563,900 | (465,000) | 2,098,900 | | |
| Total Intangible Assets | | 10,703,900 | (4,487,900) | 6,216,000 | 10,703,900 | (3,741,600) | 6,962,300 | | |
| Other Non Current Assets | | 95,000 | 3/4 | 95,000 | 84,800 | 3/4 | 84,800 | | |

All of the Company's intangible assets are amortized over their estimated useful lives. Total amortization expense for intangible assets was \$248,800 and \$746,400 for the three- and nine-month periods ended September 30, 2004 and 2003, respectively.

The estimated future amortization expense of intangible assets as of September 30, 2004 for the remainder of fiscal year 2004 and the five succeeding years is as follows:

| | Estimated Amortization |
|-------------------------------|---------------------------|
| Year ending December 31, | Expense |
| 2004 (remaining three months) | \$ 248,800 |
| 2005 | 995,100 |
| 2006 | 995,100 |
| 2007 | 956,300 |
| 2008 | 529,500 |
| 2009 | 529,500 |

(6) Net Income (Loss) Per Share

Consistent with SFAS 128, basic earnings (loss) per share amounts are based on the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share amounts are based on the weighted average number of shares of common stock and the potential common stock outstanding during the period. The Company has excluded all of the potential common stock shares from the calculation of diluted weighted average share amounts for the three-month and nine-month periods ended September 30, 2004 and 2003 as its inclusion would have been anti-dilutive. A total of 3,536,200 and 3,884,600 stock options and warrants were excluded from the computation of weighted average common shares for the periods ended September 30, 2004 and 2003, respectively, as they were anti-dilutive.

(7) Stock Options

AVANT periodically grants stock options for a fixed number of shares to employees and directors with an exercise price equal to the fair market value of the shares at the date of grant. AVANT accounts for such stock option grants using the intrinsic value method and intends to continue to do so.

During the nine month period ended September 30, 2003, the Company awarded Restricted Stock Units to its President and CEO and recorded non-cash deferred compensation amounting to \$1,104,000. The Company has recognized \$207,000 and \$46,000 as stock based compensation expense in the statement of operations during the nine month periods ended September 30, 2004 and 2003, respectively.

The following are pro forma net loss and net loss per share, as if compensation expense for the option plans had been determined based on the fair value at the date of grant:

| | Three months ended September 30, | | | | | Nine mon Septem | |
|---|-------------------------------------|-----------|----|-----------|----|--------------------|-----------------|
| | | 2004 | | 2003 | | 2004 | 2003 |
| Net Loss: | | | | | | | |
| As reported | \$ | 3,697,200 | \$ | 2,115,700 | \$ | 9,505,400 | \$ 8,661,200 |
| Less: Stock-based employee compensation expense as reported | | (69,000) | | (46,000) | | (207,000) | (46,000) |
| Add: Total stock-based employee compensation expense | | | | | | | |
| determined under fair value based method for all awards | | 251,800 | | 256,600 | | 729,100 | 688,900 |
| Pro forma | | 3,880,000 | | 2,326,300 | | 10,027,500 | 9,304,100 |
| | | | | | | | |
| Basic and Diluted Net Loss Per Share: | | | | | | | |
| As reported | \$ | 0.05 | \$ | 0.03 | \$ | 0.13 | \$ 0.14 |
| Pro forma | | 0.05 | | 0.04 | | 0.14 | 0.15 |

The fair value of the option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

| | Three months September | | Nine months o September | |
|---------------------------------|---------------------------|------------|----------------------------|------------|
| | 2004 | 2003 | 2004 | 2003 |
| Expected stock price volatility | 81% | 109% | 64% | 109% |
| Expected option term | 5 Years | 5 Years | 5 Years | 5 Years |
| Risk-free interest rate | 3.3 - 3.9% | 2.5 - 3.6% | 2.7 - 4.2% | 2.1 - 3.6% |
| Expected dividend yield | None | None | None | None |

Because additional option grants are expected to be made each year, the above pro forma disclosures are not representative of pro forma effects of reported net income for future years.

9

(8) Product Development and Licensing Agreements

AVANT's revenue from product development and licensing agreements was received pursuant to contracts with different organizations. Total revenue recognized by the Company in connection with these contracts for the three- and nine-month periods ended September 30, 2004 and 2003 were approximately \$144,300 and \$2,393,100 in 2004 and \$1,232,900 and \$1,620,000 in 2003, respectively. A summary of these contracts follows:

(A) GlaxoSmithKline plc

During 1997, AVANT entered into an agreement with GlaxoSmithKline plc ("Glaxo") to collaborate on the development and commercialization of the Company's oral rotavirus vaccine. Under the terms of the agreement, Glaxo received an exclusive worldwide license to commercialize AVANT's rotavirus vaccine. AVANT was responsible for continuing the Phase II clinical efficacy study of the rotavirus vaccine, which was completed in August 1998. Glaxo made an initial license payment of \$250,000 in 1997 upon execution of the agreement. In June 1999, AVANT received a milestone payment of \$500,000 from Glaxo for the successful completion of the Phase II clinical efficacy study and the establishment of a commercially viable process for manufacture of the vaccine. Glaxo has assumed responsibility for all subsequent clinical trials and all other development activities. Glaxo initiated global Phase III clinical trials of Rotarix® in the third quarter of 2003, and AVANT recognized a \$1.0 million milestone. In July 2004, the Mexican Board of Health approved the marketing of Rotarix® in Mexico and AVANT expects Glaxo to launch the product during the first half of 2005. AVANT has no obligation to incur any research and development costs in connection with this agreement. AVANT is obligated to maintain a license with an academic institution with respect to this agreement and incurred licensing fees of \$150,000 in both nine-month periods ended September 2004 and 2003, respectively. The term of this agreement is through the expiration of the last of the patents covered by the agreement, although Glaxo may terminate the agreement upon 90 days prior written notice. Glaxo has agreed to make further payments, which could total up to \$7.5 million, upon the achievement of specified milestones. In addition, AVANT will be entitled to royalties based on worldwide net sales of Rotarix®.

(B) Pfizer Inc

In connection with the Company's acquisition of Megan, it entered into a licensing agreement with Pfizer Inc, Animal Health Division ("Pfizer"), whereby Pfizer has licensed Megan's technology for the development of animal health and food safety vaccines. Upon execution of the agreement, Pfizer made an initial license payment of \$2.5 million together with a \$3 million equity investment. In December 2002, AVANT received a milestone payment of \$500,000 from Pfizer as a result of the submission of an application with the USDA for licensure of a food safety vaccine. Under the agreement, AVANT may receive additional milestone payments of up to \$3 million based upon attainment of specified milestones. AVANT has received research and development funding totaling \$1 million from Pfizer through November 2002 while incurring \$1,057,000 in associated research and development costs. AVANT may receive royalty payments on eventual product sales. The term of this agreement is through the expiration of the last of the patents covered by the agreement. AVANT has no obligation to incur any research and development costs in connection with this agreement.

(C) DynPort Vaccine Company LLC

In October 2001, the Company granted DynPort Vaccine Company LLC (DVC) a license for exclusive rights to use certain components of its anthrax vaccine technology. In October 2001, in connection with the execution of the agreement, AVANT received a \$200,000 materials transfer fee. Also in October 2002, DVC announced the initiation of a Phase I clinical trial of a new injectable recombinant anthrax vaccine in approximately 70 volunteers. The vaccine candidate consists of a highly purified protein—Protective Antigen—derived from the anthrax bacterium using recombinant DNA technology and production processes licensed from AVANT. Under the agreement, AVANT is also entitled to annual \$50,000 license maintenance payments, with respect to which AVANT has received \$100,000, and milestone payments of up to \$700,000 in the aggregate, \$100,000 of which AVANT received upon

10

initiation of a Phase I clinical trial in 2002. AVANT is also entitled to specified royalties on eventual product sales. The term of this agreement is through the expiration of the last of the patents covered by the agreement, although DVC may terminate the agreement upon 90 days prior written notice. DVC, a privately-held company, is chartered with providing an integrated approach for the advanced development of specific vaccines and other products to protect against the threat of biological warfare agents. DVC has a 10-year contract with the U.S. Department of Defense for the development of vaccines against certain acute infectious and contagious diseases, initiated under the 1997 Joint Vaccine Acquisition Program. AVANT has no obligation to incur any research and development costs in connection with this agreement.

During 2003, AVANT entered into an agreement with DVC for funding production of the replacement of AVANT's recombinant Protective Antigen ("rPA") clinical materials used by DVC in the Phase I clinical trial described above. Under a separate agreement with the Walter Reed Army Institute of Research (WRAIR), AVANT was obligated to provide rPA for a clinical trial. AVANT recorded the \$1 million received from DVC as deferred revenue in 2003. In 2004, the agreement with WRAIR was amended and AVANT was no longer obligated to provide rPA. Accordingly, AVANT recognized the previously deferred \$1 million as revenue in the first quarter of 2004.

(D) AdProTech

In March 2004, AVANT granted a license to AdProTech, Ltd for non-exclusive rights to use certain components of its intellectual property surrounding complement inhibition. In April 2004, AVANT received an initial license payment of \$1 million from AdProTech and AdProTech was acquired by Inflazyme Pharmaceuticals Ltd. which assumed the license. AVANT has no continuing involvement or obligation under this license agreement, thus it recognized the \$1 million as revenue during the first quarter of 2004. Under the agreement, AVANT is entitled to annual license fees, milestone payments of up to \$13.5 million in the aggregate and royalties on eventual product sales. AVANT has no obligations to incur any research and development costs in connection with this agreement.

(9) <u>Direct Equity Placement</u>

In February 2004, AVANT completed a direct equity placement of 8,965,000 shares of common stock to institutional investors at a price of \$2.75 per share which generated gross proceeds totaling approximately \$24.7 million. Expenses associated with the transaction totaled approximately \$1,602,800.

(10) Note Payable

In December 2003, AVANT entered into a Lease Agreement, a Secured Promissory Note: Equipment Loan and a Security Agreement with the Massachusetts Development Finance Agency ("MassDevelopment"), an economic development entity for the Commonwealth of Massachusetts, for AVANT to occupy and build-out a pilot manufacturing facility in Fall River, Massachusetts. Under the Lease Agreement, AVANT is eligible for a Specialized Tenant Improvement Allowance of up to \$1,027,800 to finance the build-out of the Fall River facility. AVANT may draw down monthly disbursement increments against the Allowance but must use the Allowance within the first twelve months of the original lease term. Principal and interest payments of the aggregate

disbursement increments are due monthly using an amortization period of 15 years and an interest rate of 5.5% per annum. At September 30, 2004, AVANT had requested drawn downs totalling approximately \$342,700.

Under the Secured Promissory Note: Equipment Loan, AVANT may request advances of principal up to \$1,104,000 from MassDevelopment to finance the purchases of equipment to be placed in the Fall River facility. The Loan has a term of 84 months at an interest rate of 5.5% per annum and must be drawn down within the first twelve months from the date of the Note. The Loan is collateralized by all of the equipment purchased with the principal amount. At September 30, 2004, AVANT had not requested any advances against the Equipment Loan. In addition, under the Lease Agreement if AVANT does not draw down upon the entire \$1,104,000 principal amount it may, by written notice to MassDevelopment, draw upon

11

and utilize up to the lesser of (i) \$200,000 or (ii) the undrawn upon amount of the Equipment Loan, as part of the Specialized Tenant Improvement Allowance described above.

(11) Commitments and Contingencies

(A) Commitments for the Build-out of the Fall River Facility

In August 2004, AVANT entered into a Design/Build Contract totaling \$1,917,700 with a design/builder for the build-out of the Fall River facility. The final contract amount may be subject to change as a result of work change orders which may arise during the construction period. As of September 30, 2004, AVANT had made payments and accrued costs totaling \$666,400 under the Contract.

(B) Purchase Commitments for Contract Manufacturing

In April 2000, AVANT entered into a Services Agreement (the "Lonza Agreement") with Lonza Biologics plc ("Lonza") for process development and manufacture of its product candidate TP10. During the quarter ended September 30, 2004, AVANT entered into a number of amendments to the Lonza Agreement for specific process development and scale-up work totaling approximately \$917,100. The Company incurred \$969,300 of expense related to the Lonza Agreement in the nine months ended September 30, 2004 of which \$874,400 remained accrued at September 30, 2004.

In May 2004, AVANT signed an Amendment to the Lonza Agreement for the cGMP production of TP10 at commercial scale scheduled for the first quarter of 2005. Under the terms of the Lonza Agreement, if AVANT voluntarily terminates the Amendment within four months of the expected start date of the cGMP production run, AVANT is obligated to pay a termination fee of approximately \$720,000. At September 30, 2004, AVANT was within the fourmonth period of the expected start of the cGMP production run. AVANT currently has no plans to terminate this production run.

12

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995: This quarterly report on Form 10-O includes forward-looking statements that are subject to a variety of risks and uncertainties and reflect AVANT's current views with respect to future events and financial performance. There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statements made by AVANT. These factors include, but are not limited to: (1) the integration of multiple technologies and programs; (2) the ability to adapt AVANT's vectoring systems to develop new, safe and effective orally administered vaccines against anthrax and plaque or any other microbes used as bioweapons and other disease causing agents; (3) the ability to successfully complete development and commercialization of TP10, CholeraGardeÔ (Peru-15), Ty800, CETi-1, Therapore® and of other products: (4) the cost, timing, scope and results of ongoing safety and efficacy trials of TP10. CholeraGardeÔ (Peru-15), Tv800. CETi-1, Therapore® and other preclinical and clinical testing; (5) the ability to successfully complete product research and further development, including animal, pre-clinical and clinical studies of TP10, CholeraGardeÔ (Peru-15), Ty800, CETi-1, Therapore® and other products; (6) the ability of the Company to manage multiple late stage clinical trials for a variety of product candidates; (7) royalty revenues from product sales of Rotarix®, Megan®Vac 1, Megan®Eqq and other future products; (8) changes in existing and potential relationships with corporate collaborators; (9) the cost, delivery and quality of clinical and commercial grade materials supplied by contract manufacturers; (10) the timing, cost and uncertainty of obtaining regulatory approvals to use TP10, for among other purposes, adults undergoing cardiac surgery, to use CholeraGardeÔ (Peru-15) and Ty800, among other purposes, to protect travelers and people in endemic regions from diarrhea causing diseases, to use CETi-1, among other purposes, to raise serum HDL cholesterol levels and for other products; (11) the ability to obtain substantial additional funding; (12) the ability to develop and commercialize products before competitors; (13) the ability to retain certain members of management; and (14) other factors detailed from time to time in filings with the Securities and Exchange Commission. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences. These forwardlooking statements were based on information, plans and estimates at the date of this report, and we do not promise to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

Item 2. Management's Discussion and Analysis of Financial Condition And Results of Operations

AVANT's principal activity since our inception has been research and product development conducted on its own behalf, as well as through joint development programs with several pharmaceutical companies and other collaborators. AVANT was incorporated in the State of Delaware in December 1983.

CRITICAL ACCOUNTING POLICIES

The Company's critical accounting policies are set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 to our 2003 Form 10-K. There have been no changes to these policies since December 31, 2003. Readers are encouraged to review these critical accounting policies in conjunction with the review of this Form 10-Q.

OVERVIEW

AVANT's focus is unlocking the power of the immune system to prevent and treat disease. The Company has assembled a broad portfolio of technologies and intellectual property that give it a strong competitive position in vaccines and immunotherapeutics. These include an oral human rotavirus

The Company has actively developed and acquired innovative technologies – especially novel approaches to vaccine creation. The development of immunotherapeutic vaccines like CETi-1 and the marriage of innovative vector delivery technologies with the unique VitriLife® manufacturing process represent the potential for a new generation of vaccines. In addition, AVANT's vaccine technology can provide rapid protection against bacterial illnesses which may prove useful for improving and expanding America's vaccine arsenal against microbial agents used in war or terrorist attacks.

AVANT is targeting its efforts where it can add the greatest value to the development of its products and technologies. Its goal is to demonstrate clinical proof-of-concept for each product, and then seek excellent partners to help see those products through to commercialization. This approach allows AVANT to maximize the overall value of its technology and product portfolio while best ensuring the expeditious development of each individual product.

ACQUISITIONS

Universal Preservation Technologies, Inc.: In January 2003, AVANT completed the acquisition of certain technology and intellectual property of Universal Preservation Technologies, Inc. (UPT), a privately held company, and the licensure of certain patent rights from Elan Drug Delivery Limited (EDD), a subsidiary of Elan Corporation plc. EDD's license to AVANT gives AVANT exclusive rights to the VitriLifeÒ process for use in orally administered vaccines and certain other non-injectable applications, and non-exclusive rights in certain other fields. VitriLife® is a patented drying method for the industrial-scale preservation of biological solutions and suspensions, such as proteins, enzymes, viruses, bacteria and other cells, which has the potential to cut production costs and improve product stability at room temperature or higher. AVANT has determined that this technology has alternative future uses and will be incorporated into a number of AVANT's bacterial vaccine programs. AVANT paid an aggregate of \$2,000,000 in consideration in the transaction, recorded this value to acquired intangible assets, and is amortizing these assets over their estimated lives of ten years.

Megan Health, Inc.: On December 1, 2000, AVANT acquired all of the outstanding capital stock of Megan Health, Inc. ("Megan"), a company engaged in the discovery and development of human and animal vaccines using patented gene modification technologies. In connection with the acquisition, AVANT recorded a charge of \$9,012,300 for acquired in-process research and development ("IPR&D"), which represented purchased in-process technology which had not yet reached technological feasibility and had no alternative future use. As of September 30, 2004, none of the acquired research and development projects had reached technological feasibility.

Virus Research Institute, Inc.: On August 21, 1998, AVANT acquired Virus Research Institute, Inc. ("VRI"), a company engaged in the discovery and development of systems for the delivery of vaccines and immunotherapeutics, and novel vaccines for adults and children. In connection with the acquisition, AVANT recorded a charge of \$44,630,000 for acquired IPR&D, which represented purchased in-process technology which had not yet reached technological feasibility and had no alternative future use. As of September 30, 2004, only RotarixÒ of the acquired research and development projects had reached technological feasibility as it received marketing approval in Mexico.

RESEARCH AND DEVELOPMENT ACTIVITIES

AVANT is currently focused on the development of a number of immunotherapeutic and vaccine product candidates which are in various stages of clinical trials. AVANT expects that a large percentage of its research and development expenses will be incurred in support of its current and future clinical trial programs.

The expenditures that will be necessary to execute AVANT's business plan are subject to numerous uncertainties. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product

14

candidate. It is not unusual for the clinical development of these types of product candidates to each take five years or more, and for total development costs to exceed \$100 million for each product candidate. AVANT estimates that clinical trials of the type AVANT generally conducts are typically completed over the following timelines:

| Estimated Completion Period |
|-----------------------------------|
| |
| 1-2 Years |
| 1-5 Years |
| 1-5 Years |
| |

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that seems appropriate in view of results;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patient subjects; and
- the efficacy and safety profile of the product candidate.

AVANT tests potential product candidates in numerous preclinical studies for safety, toxicology and immunogenicity. AVANT then may conduct multiple clinical trials for each product candidate. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain product candidates in order to focus our resources on more promising product candidates.

An element of AVANT's business strategy is to pursue the research and development of a broad portfolio of product candidates. This is intended to allow AVANT to diversify the risks associated with its research and development expenditures. As a result, AVANT believes its future capital requirements and its future financial success are not substantially dependent on any one product candidate. To the extent AVANT is unable to maintain a broad range of product candidates, AVANT's dependence on the success of one or a few product candidates increases.

AVANT's product candidates also have not yet received FDA regulatory approval, which is required before AVANT can market them as therapeutic or vaccine products in the U.S. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, the FDA must conclude that AVANT's clinical data establish safety and efficacy. Historically, the results from preclinical testing and early clinical trials (through Phase II) have often not been predictive of results obtained in later clinical trials. A number of new drugs, biologics and vaccines have shown promising results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

Furthermore, AVANT's business strategy includes the option of entering into collaborative arrangements with third parties to complete the development and commercialization of AVANT's product candidates. In the event that third parties take over the clinical trial process for one of AVANT's product candidates, the estimated completion date would largely be under control of that third party rather than AVANT. AVANT cannot forecast with any degree of certainty which proprietary products, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect AVANT's development plan or capital requirements. AVANT's programs may also benefit from subsidies, grants, contracts or government or agency-sponsored studies that could reduce AVANT's development costs.

15

As a result of the uncertainties discussed above, among others, AVANT is unable to estimate the duration and completion costs of its research and development projects or when, if ever, and to what extent it will receive cash inflows from the commercialization and sale of a product. AVANT's inability to complete its research and development projects in a timely manner or its failure to enter into collaborative agreements, when appropriate, could significantly increase its capital requirements and could adversely impact its liquidity. These uncertainties could force AVANT to seek additional, external sources of financing from time to time in order to continue with its business strategy. AVANT's inability to raise additional capital, or to do so on terms reasonably acceptable to it, would jeopardize the future success of its business. The amount incurred for each material research program since the beginning of 2001 is set forth below under "Program Developments." During the past five years through the end of 2003, AVANT incurred an aggregate of \$65.0 million in research and development costs. During the nine months ended September 30, 2004, AVANT incurred an aggregate of \$9.6 million in research and development costs. The following table indicates the amount incurred for each of AVANT's material research programs and for other identified research and development activities during the three years ended December 31, 2003, 2002, and 2001 and the nine-month periods ended September 30, 2004 and 2003. The amounts disclosed in the following table and in "Program Developments" below reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program. Prior to January 1, 2000, AVANT did not track research and development costs by program and therefore we are unable to disclose spending by program prior to that date.

| | Nine Months Ended September 30, | | | Year Ended December 31, | | | | | | |
|---------------------------------------|------------------------------------|-----------|----|----------------------------|----|------------|----|------------|----|------------|
| | | 2004 | | 2003 | | 2003 | | 2002 | | 2001 |
| Bacterial Vaccines: | | | | | | | | | | |
| CholeraGardeÔ | \$ | 80,700 | \$ | 929,200 | \$ | 695,800 | \$ | 5,959,100 | \$ | 2,369,200 |
| Ty800 | | 545,900 | | 303,100 | | 186,300 | | 2,203,600 | | 1,863,500 |
| Other | | 233,300 | | 125,600 | | 137,500 | | 204,400 | | _ |
| BioDefense Vaccines: | | 2,634,700 | | 2,559,100 | | 3,524,500 | | 239,900 | | _ |
| Cholesterol Management Vaccine: | | | | | | | | | | |
| CETi-1 | | 621,900 | | 2,771,200 | | 3,404,000 | | 3,176,800 | | 2,387,700 |
| Complement Inhibitors: | | | | | | | | | | |
| TP10/TP20 | | 4,906,000 | | 712,200 | | 1,648,700 | | 1,714,800 | | 12,930,500 |
| Food Safety & Animal Health Vaccines: | | 11,600 | | 46,300 | | 49,400 | | 450,600 | | 984,900 |
| Viral Vaccines: | | | | | | | | | | |
| Rotavirus vaccine | | 150,000 | | 375,000 | | 200,000 | | 400,000 | | 334,100 |
| Other | | 196,800 | | 54,300 | | 72,400 | | 346,800 | | 264,600 |
| Other Programs: | | 263,800 | | _ | | 102,700 | | _ | | _ |
| Discontinued Programs: | | _ | | _ | | _ | | 12,500 | | 446,000 |
| | | | | | | | | | | |
| Total R&D Expense | \$ | 9,644,700 | \$ | 7,876,000 | \$ | 10,021,300 | \$ | 14,708,500 | \$ | 21,580,500 |

PROGRAM DEVELOPMENTS

Rotavirus Vaccine: Rotavirus is a major cause of diarrhea and vomiting in infants and children. No vaccine against rotavirus is currently on the market. In 1997, AVANT licensed its oral rotavirus vaccine to Glaxo. In 1999, after the Company's Phase II study demonstrated 89% protection in a study involving 215 infants, Glaxo paid AVANT an additional license fee and assumed full responsibility for funding and performing all remaining clinical development. Substantially all of the ongoing development is being conducted and funded by Glaxo. During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$1.1 million in licensing fees and \$79,000 in research and development costs. During the nine months ended September 30, 2004, AVANT incurred approximately \$150,000 in licensing

Asia using its two-dose oral rotavirus vaccine, called Rotarix®. Glaxo initiated global Phase III clinical trials of Rotarix® in the third quarter of 2003 and AVANT recognized a \$1.0 million milestone. In July 2004, the Mexican Board of Health approved the marketing of Rotarix® in Mexico. Assuming product development and commercialization continues satisfactorily, AVANT may receive additional milestone payments totaling \$7.5 million upon the achievement of specified milestones. In addition, AVANT will be entitled to royalties based on worldwide net sales of Rotarix®.

Complement Inhibitors: In February 2002, AVANT announced that TP10 had shown a trend but had not achieved a significant reduction in the primary endpoint of death, myocardial infarction, prolonged intubation or prolonged intra-aortic balloon pumping following preliminary analysis of a Phase II adult cardiac surgery trial conducted in 564 patients. However, further analysis of the study data demonstrated an important treatment benefit to male patients participating in the trial, with no significant treatment benefit to female patients. The important treatment benefits seen in the male population were directly related to the combined incidence of acute myocardial infarction and mortality rate. Adverse events reported following treatment with TP10 were generally similar to those seen in placebo treated patients and were assessed by investigators to be routinely observed following cardiopulmonary bypass surgery.

AVANT is currently conducting a Phase IIb double-blind, placebo-controlled trial of TP10 in approximately 300 high risk women undergoing cardiopulmonary bypass surgery. The trial will assess the safety and efficacy of TP10 versus placebo, will be conducted at approximately 30 sites throughout the United States, and study results are expected to be reported out in the first half of 2005. The goals of the trial are to determine the safety of TP10 in female patients undergoing cardiac bypass surgery and provide additional efficacy data that will be supportive to start the Phase III trial. AVANT is working closely with its manufacturing partner, Lonza Biologics plc, to complete process development and scale-up efforts in preparation for the production of Phase III clinical materials and the start of that trial by year-end 2005.

During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$22.8 million in research, development and clinical costs. During the nine months ended September 30, 2004, AVANT incurred approximately \$4.9 million in research, development, contract manufacturing and clinical costs associated with its complement programs. AVANT is seeking partnering arrangements for a worldwide license to capture the value inherent in this program and its strong intellectual property portfolio.

Bacterial Vaccines: AVANT's goal is to become a leading developer of innovative vaccines that address health care needs on a global basis. In this regard, AVANT acquired VitriLife®, a technology with the potential to reduce manufacturing costs and improve product stability, eliminating the need for vaccine refrigeration during shipping and storage. With this technology and AVANT's *Cholera*- and *Salmonella*-vectored delivery technologies, named VibrioVec™ and SalmoVec™, the Company can now develop a new generation of vaccines that have an ideal product profile: safe, effective, oral, single-dose, rapidly protective and requiring no refrigeration.

Development of a safe, effective cholera vaccine is the first step in establishing AVANT's single-dose, oral bacterial vaccine franchise. During 2002, AVANT completed a Phase II dose-ranging study with CholeraGarde® which confirmed the safety and activity of this vaccine and supported the start of Phase II trials in December 2002 with the International Vaccine Institute (IVI) in Bangladesh where cholera is endemic. IVI is assessing the safety and immunogenicity of the vaccine in adults and progressively younger pediatric populations, eventually studying the vaccine in infants as young as nine months. To date, IVI has completed testing in adults and toddlers, ages 2 to 5 years, and is now vaccinating infants, ages 9 to 23 months. In January 2004, AVANT announced positive preliminary results of the adult portion from the Phase II clinical trial of CholeraGarde® in Bangladesh. In 70 adult subjects, vaccination with the single-dose, oral cholera vaccine was well tolerated. Moreover, over 70% of the vaccinated adults responded with a favorable immune response. The study is expected to complete around year-end 2004.

17

During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$9.2 million in research, development and clinical costs on its CholeraGarde® program. During the nine months ended September 30, 2004, AVANT incurred approximately \$80,700 in research, development and clinical costs on its CholeraGarde® program.

AVANT is also developing an oral typhoid fever vaccine, Ty800, for global health needs. The National Institute of Allergy and Infectious Disease (NIAID) of the National Institutes of Health (NIH) and AVANT have agreed for the NIAID to conduct a Phase I in-patient dose-ranging clinical trial aimed at demonstrating the safety and immunogenicity of the Ty800 vaccine. The trial is planned for a NIAID-funded clinical site using NIAID-funded clinical material. The NIAID trial seeks to confirm the safety and immunogenicity of the Ty800 oral vaccine observed in an earlier physician-sponsored Ty800 vaccine study. During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$4.3 million in research, development and clinical costs on its Ty800 program. During the nine months ended September 30, 2004, AVANT incurred approximately \$545,900 in research, development and clinical costs on its Ty800 program.

Finally, AVANT is developing three additional bacterial vaccines against enterotoxigenic *E. coli*, *Shigella* and *Campylobacter*—all important causes of serious diarrheal diseases worldwide. These three programs are in pre-clinical development. In 2004, AVANT expects to allocate resources to further the development of a two-vaccine combination product containing ETEC and Campylobacter addressed to the travelers' market.

BioDefense Vaccines: The attenuated live bacteria used to create AVANT's single-dose oral vaccines can also serve as vectors for the development of vaccines against other bacterial and viral diseases. By engineering key disease antigens into the DNA of the vector organisms, AVANT expects to be able to extend the protective ability of its single-dose oral vaccines to a wide variety of illnesses. AVANT believes its vector technologies may prove useful for improving and expanding America's vaccine arsenal against microbial agents used in war or terrorist attacks.

In October 2001, AVANT granted DynPort Vaccine Company LLC (DVC) a license for exclusive rights to use certain components of AVANT's anthrax vaccine technology. In October 2002, DVC announced the initiation of a Phase I clinical trial of a new injectable recombinant anthrax vaccine in approximately 70 volunteers. The vaccine candidate consists of a highly purified protein—Protective Antigen—derived from the anthrax bacterium using recombinant DNA technology and production processes licensed from AVANT. DVC hopes this injectable vaccine will offer a safe, effective product to support the country's need for a new-generation anthrax vaccine. The study will evaluate tolerability, safety and immunogenicity of DVC's new vaccine. In June 2003, AVANT was awarded a subcontract by DVC, in the amount of \$344,000, which covers stability testing of DVC's injectable anthrax vaccine. Payments under the subcontract agreement are made on a time and materials basis and receipt of the full amount is conditioned upon AVANT performing and continuing to demonstrate that it has the capability to perform the funded work.

Further, in January 2003, AVANT was awarded a subcontract to develop for the U.S. Department of Defense (DoD) an oral combination vaccine against anthrax and plague using AVANT's proprietary vaccine technologies. AVANT executed this initial subcontract with DVC and will be reimbursed on a time and materials basis for vaccine development research work performed by AVANT in the amount of \$2.5 million. In June 2003, AVANT was awarded a

second subcontract for approximately \$1.3 million to support preclinical animal testing of vaccine constructs being developed by AVANT for the oral combination vaccine against anthrax and plague. In April 2004, AVANT was awarded a third subcontract for approximately \$3 million to support the human clinical testing of a plague vaccine candidate being developed by AVANT for use in the oral combination vaccine. The Defense Appropriations Bill for Fiscal Year 2005 passed by Congress in July 2004 commits \$2.8 million for the continued development of this combination vaccine. Payments under the subcontract agreement are made on a time and materials basis and receipt of the full amount is conditioned upon the project being fully funded through completion and AVANT performing and continuing to demonstrate that it has the capability to perform the funded work.

18

During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$3.8 million in research and development costs on its biodefense vaccine program. During the nine months ended September 30, 2004, AVANT incurred approximately \$2.6 million in research and development costs on its biodefense vaccine program.

Food Safety and Animal Health Vaccines: AVANT has partnered with Pfizer, who will apply AVANT's vaccine technologies to animal health and human food safety markets. The Pfizer research program achieved an important milestone in late 2002, which resulted in a payment of \$500,000 to AVANT. During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$1.5 million in research and development costs on its food safety and animal health vaccines program. During the nine months ended September 30, 2004, AVANT incurred approximately \$11,600 in research and development costs on its food safety and animal health vaccines program.

Cholesterol Management Vaccine: AVANT is developing an immunotherapeutic vaccine against endogenous cholesteryl ester transfer protein ("CETP"), which may be useful in reducing risks associated with atherosclerosis. CETP is a key intermediary in the balance of HDL (high-density lipoprotein) and LDL (low-density lipoprotein). The Company is developing this vaccine, CETi-1, to stimulate an immune response against CETP, which it believes may improve the ratio of HDL to LDL cholesterol and reduce the progression of atherosclerosis which leads to heart attack. AVANT has conducted preliminary studies of rabbits, which have demonstrated the ability of CETi-1 vaccine to elevate HDL and reduce the development of fatty legions in the blood vessels.

CETi-1 is being developed for the management of patients with low levels of HDL cholesterol. In September 1999, AVANT initiated a double-blind placebo controlled, Phase I clinical trial of our CETi-1 vaccine in adult volunteers. The object of the study was to demonstrate the safety of single administrations of the vaccine at four different dosage strengths and results were announced in January 2001. The vaccine was very well tolerated in the 48 adult volunteers who participated in the study. The only serious adverse reaction reported during the study was not related to study medication. There were no differences in the safety profiles of placebo groups and active vaccine groups. In addition, there was limited evidence of an immune response in one subject treated with the highest dose. Subsequently, AVANT announced results from a double-blinded placebo controlled extension of the earlier completed CETi-1 Phase I trial in the same healthy adult volunteers receiving a second dose of the vaccine. Results from the extension study showed measurable antibody titers in all dose groups treated with active study medication, suggesting a dose-response relationship.

These data were helpful in moving the program forward to a placebo controlled Phase II study, which was initiated in August 2001, in approximately 200 patients with low levels of HDL cholesterol. The objectives of the study were to evaluate the safety, immunogenicity and dose-response relationship of the CETi-1 product in patients who receive an initial immunization followed by boosters. The primary endpoint was the change in HDL cholesterol measured after the six-month booster. In October 2003, AVANT completed the CETi-1 vaccine Phase II efficacy study. The results of the study demonstrated proof-of-concept in humans confirming that blocking cholesterol transfer could raise HDL levels. In addition, the CETi-1 vaccine worked as designed to elicit anti-CETP antibodies in a high percentage of patients treated, approximately 90%. AVANT is currently evaluating a number of new adjuvants and delivery technologies for its CETP vaccine in animal models and expect to choose the approach eliciting the most robust antibody response around year-end 2004. During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$10.9 million in research, development and clinical costs associated with the CETi program. During the nine months ended September 30, 2004, AVANT incurred approximately \$621,900 in research, development and clinical costs associated with the CETi program. AVANT plans to seek a corporate partner to complete development and to commercialize the CETi vaccine.

19

TECHNOLOGY LICENSING

AVANT has adopted a business strategy of out-licensing technology that does not match its development focus or where it lacks sufficient resources for the technology's efficient development. For example, when AVANT acquired Megan it also signed an agreement with Pfizer Inc to leverage the value of Megan's oral vaccine technology in a significant market opportunity (animal health and human food safety) outside of AVANT's own focus on human health care.

DynPort License: In October 2001, AVANT granted a license to DynPort Vaccine Company LLC (DVC) for exclusive rights to use certain components of AVANT's vaccine technology. Financial terms of the agreement with DVC include license fees, milestone payments and royalties.

AdProTech: In March 2004, AVANT granted a license to AdProTech, Ltd for non-exclusive rights to use certain components of its intellectual property surrounding complement inhibition. Financial terms of the agreement with AdProTech include license fees, milestone payments and royalties.

RESULTS OF OPERATIONS

Three-Month Period Ended September 30, 2004 as Compared with the Three-Month Period Ended September 30, 2003

AVANT reported consolidated net loss of \$3,697,200, or \$.05 per share, for the third quarter ended September 30, 2004, compared with a net loss of \$2,115,700, or \$.03 per share, for the third quarter ended September 30, 2003. The weighted average common shares outstanding used to calculate net loss per common share was 74,118,300 in 2004 and 64,703,000 in 2003.

Revenue: Total revenue decreased \$1,487,500, or 73.8%, to \$527,600 for the third quarter of 2004 compared to \$2,015,100 for the third quarter of 2003.

Product development and licensing revenue decreased \$1,088,600, or 88.3%, to \$144,300 in 2004 from \$1,232,900 in 2003. Product development and licensing revenue in 2004 consisted primarily of the amortization of nonrefundable license fees from Pfizer. The remaining Pfizer license fees totaling \$82,900 will be fully amortized by November 2004. In addition to the recognition of Pfizer license fees in the third quarter of 2003, AVANT also recognized a \$1 million milestone payment from Glaxo.

In 2003 and 2004, AVANT was awarded Department of Defense subcontracts from its partner, DVC, that supports the development of an oral, combination vaccine against both anthrax and plague using the Company's vectored vaccine technology. AVANT will be reimbursed by DVC on a time and materials basis for vaccine development research work performed by AVANT in the amount of approximately \$6.8 million. Under these agreements and several SBIR grants, AVANT recognized \$334,200 and \$733,700 in government contract and grant revenue during the third quarters of 2004 and 2003, respectively, for work performed.

In 2002, AVANT transferred the marketing and distribution of the Megan poultry product line to its partner, Lohmann Animal Health International (LAHI), and AVANT receives a royalty percentage of all Megan®Vac 1 and Megan®Egg product sales. Royalty payments received during the third quarter of 2004 and 2003 totaled \$49,100 and \$48,500, respectively. Megan®Vac 1 and Megan®Egg are vaccines for use in chickens for protection against multiple strains of *Salmonella* bacteria.

Operating Expense: Total operating expense increased \$162,600, or 3.9%, to \$4,345,200 for the third quarter of 2004 compared to \$4,182,600 for the third quarter of 2003. The increase in total operating expense in 2004 primarily results from an increase in research and development expense in the third quarter of 2004 as a result of increased clinical trials costs and contract manufacturing costs to support the Company's TP10 program and the ramp-up of Fall River personnel and facility costs during the ongoing build-out process.

20

Research and development expense increased \$295,700, or 11.8%, to \$2,805,800 in 2004 from \$2,510,100 in 2003. The increase in 2004 compared to 2003 is primarily due to an increase in clinical trials costs of \$260,900 and contract manufacturing costs for clinical trial materials of \$118,800, both incurred on the TP10 program. The increase in research and development expense further resulted from increases in personnel and related expenses of \$49,200 and clinical trials insurance expenses of \$29,600, offset in part by declines in laboratory supplies and services expenses of \$23,500, research and development consultancy costs of \$50,100, and license fees of \$71,500. Work by Lonza, AVANT's manufacturing partner for TP10, on process development and scale-up during the first nine months of 2004 progressed at a slower than anticipated pace. AVANT expects research and development expense to increase substantially in the fourth quarter of 2004 and in 2005 as the TP10 Phase II female clinical trial continues towards full enrollment and as Lonza conducts process development and scale-up work in preparation for the production of Phase III clinical materials in 2005. Contract manufacturing expenses are likely to fluctuate from quarter to quarter as the program proceeds.

General and administrative expense decreased \$133,100, or 9.3%, to \$1,290,600 in 2004 compared to \$1,423,700 in 2003 and is primarily attributed to a decrease in legal costs of \$295,900, offset in part by increases in personnel and related costs of \$113,500, other professional fees of \$30,100, and business development consultancy costs of \$31,800.

Amortization expense of acquired intangible assets was \$248,800 in 2004 and 2003.

Investment and Other Income, *Net:* Interest and other income increased \$68,600 to \$120,400 for the third quarter of 2004 compared to \$51,800 for the third quarter of 2003. The increase is primarily due to higher cash balances during the third quarter of 2004 compared to the third quarter of 2003. During the third three months of 2004 and 2003, the average month-end cash balances were \$36,502,300 and \$24,561,200, respectively. The effective interest rates during the third three months of 2004 and 2003 were 1.32% and 0.98%, respectively.

Nine-Month Period Ended September 30, 2004 as Compared with the Nine-Month Period Ended September 30, 2003

AVANT reported a consolidated net loss of \$9,505,400, or \$.13 per share, for the nine months ended September 30, 2004, compared with a net loss of \$8,661,200, or \$.14 per share, for the nine months ended September 30, 2003. The weighted average common shares outstanding used to calculate net loss per common share was 72,510,600 in 2004 and 61,773,500 in 2003.

Revenue: Total revenue increased \$676,100 to \$4,451,300 for the first nine months of 2004 compared to \$3,775,200 for the first nine months of 2003.

Product development and licensing revenue increased \$773,100, or 47.7%, to \$2,393,100 for the first nine months of 2004 from \$1,620,000 for the first nine months of 2003. The increase is primarily due to the one-time recognition of \$1 million in revenue from DVC for rPA clinical materials and a license fee of \$1 million from AdProTech, Ltd., offset in part by the recognition in 2003 of a \$1 million milestone payment from Glaxo.

AVANT has received a number of subcontracts from its partner, DVC, to develop anthrax and plague vaccines for the U.S. Department of Defense. AVANT will be reimbursed by DVC on a time and materials basis for vaccine development research work performed by AVANT. Under these agreements and several SBIR grants, AVANT recognized \$1,928,800 and \$2,029,300 in government contract and grant revenue during the first nine months of 2004 and 2003, respectively. AVANT expects the amount of research work to be performed for DVC during the last quarter of 2004 to approximate the amount of research work performed during the third quarter of 2004.

21

Operating Expense: Total operating expense increased \$1,603,100, or 12.7%, to \$14,225,600 for the first nine months of 2004 compared to \$12,622,500 for the first nine months of 2003. The increase in total operating expense for the first nine months of 2004 compared to the first nine months of 2003 is primarily due to an increase in costs associated with conducting clinical trials and contract manufacturing efforts associated with process development and scale-up work to support AVANT's TP10 program and the ramp-up of Fall River personnel and facility costs during the ongoing build-out process.

Research and development expense increased \$1,750,800, or 22.2%, to \$9,626,800 for the first nine months of 2004 compared to \$7,876,000 for the first nine months of 2003. The increase in 2004 compared to 2003 is primarily due to increases in contract manufacturing costs for clinical trial materials of \$1,042,300, clinical trial costs of \$1,040,700 both associated with the TP10 program, laboratory supplies and services expenses of \$79,900, and clinical trials insurance expenses of \$100,300. These increases were offset in part by declines in license fees of \$414,900, research and development consultancy costs of \$146,000, and facility related expenses of \$48,700. AVANT expects research and development expense to increase substantially in 2005 as the TP10 Phase II female clinical trial reaches full enrollment, as AVANT's contract manufacturer completes process development and scale-up work and completes the production of Phase III clinical materials and as the Fall River facility is brought to full operational status.

General and administrative expense decreased \$147,700, or 3.7%, to \$3,852,400 for the first nine months of 2004 compared to \$4,000,100 for the first nine months of 2003. The decrease in 2004 is primarily attributed to decreases in legal expenses of \$464,400 and insurance expenses of \$19,000, offset partly by increased personnel and related expenses of \$236,600 and other professional fees of \$97,500. AVANT expects general and administrative expense during the fourth quarter of 2004 to approximate the expense incurred quarterly during the first nine months of 2004 and 2003.

Amortization expense of acquired intangible assets was \$746,400 in the first nine months of 2004 and 2003.

Investment and Other Income, Net: Net investment and other income increased \$82,800, or 44.5%, to \$268,900 for the first nine months of 2004 compared to \$186,100 for the first nine months of 2003. The increase is primarily due to higher average cash balances during the first nine months of 2004 compared to the first nine months of 2003. During the first nine months of 2004 and 2003, the average month-end cash balances were \$36,938,200 and \$21,088,800, respectively. The effective interest rates during the first nine months of 2004 and 2003 were 1.08% and 1.16%, respectively.

LIQUIDITY AND CAPITAL RESOURCES

AVANT has financed its operations primarily through license fees, research and development funding from the Company's collaborative partners, funding from government contracts and grants, product sales and product royalties, the private and public placement of its equity securities and debt or lease financings.

At September 30, 2004, AVANT's principal sources of liquidity consisted of cash and cash equivalents of \$35,228,300. AVANT's cash and cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of time deposits and investments in money market mutual funds with commercial banks and financial institutions, short-term commercial paper, and U.S. Government and other investment grade debt securities. Also, the Company maintains cash balances with financial institutions in excess of insured limits. AVANT does not anticipate any losses with respect to such cash balances.

22

The use of AVANT's cash flows for operations has primarily consisted of salaries and wages for its employees, facility and facility-related costs for its offices and laboratories, fees paid in connection with preclinical studies, clinical studies, contract manufacturing, laboratory supplies and services, consulting fees, and legal fees. To date, the primary sources of cash flows from operations have been payments received from the Company's collaborative partners and from government entities. In general, AVANT's sources of cash flows from operations for the foreseeable future will be upfront license payments, payments for the achievement of milestones, product royalty payments, payments under government contracts and grants and funded research and development under collaboration agreements that AVANT may receive. The timing of any new collaboration agreements, government contracts or grants and any payments under these agreements, contracts or grants cannot be easily predicted and may vary significantly from quarter to quarter.

Net cash used in operating activities decreased to \$6,812,300 for the first nine months of 2004 compared to \$8,455,900 for the first nine months of 2003. The decrease is primarily attributed to a decrease in accounts receivable, which related to a \$1,000,000 up-front payment received for a licensing agreement with AdProTech and an increase in accounts payable and accrued expenses, offset partly by the increase in net loss incurred in 2004 compared to 2003 and a decrease in deferred revenue, which related to the recognition of \$1 million from DVC. AVANT expects that cash used in operations will continue to increase as the Company continues to develop its products in clinical trials, contacts for the manufacture of clinical materials, brings it Fall River facility to full operational status and advances new products into preclinical development. The expected increase in cash used would be partially offset by anticipated payments made under the Company's government contracts and grants and anticipated product royalty payments.

Cash used in investing activities decreased to \$1,568,100 for the first nine months of 2004 compared to \$2,310,600 for the first nine months of 2003. The decrease is primarily due to \$2 million of cash paid in 2003 for certain assets of Universal Preservation Technologies, Inc., offset in part by increased investment in property and equipment in 2004 compared to 2003. AVANT expects it will continue to use cash in its investing activities as the Company expands its infrastructure and completes the build-out and validation of the Fall River pilot manufacturing facility.

Net cash provided by financing activities was \$23,357,700 for the first nine months of 2004 compared to \$9,194,200 for the first nine months of 2003. The increase is due primarily to the completion of a direct equity placement in 2004.

AGGREGATE CONTRACTUAL OBLIGATIONS

The following table summarizes AVANT's contractual obligations at September 30, 2004 and the effect such obligations and commercial commitments are expected to have on its liquidity and cash flow in future years. These obligations, commitments and supporting arrangements represent payments based on current operating forecasts, which are subject to change:

| | Total | Less than One Year | 1-3 Years | 3-5 Years | 4-5 Years |
|-----------------------------|-----------------|-----------------------|-----------------|---------------|---------------|
| Contractual obligations: | | | | | |
| Operating lease obligations | \$ 9,319,500 | \$ 2,332,400 | \$ 6,100,000 | \$ 605,600 | \$ 281,500 |
| Licensing obligations | 920,000 | 310,000 | 355,000 | 170,000 | 85,000 |

| Construction contracts Total contractual obligations | \$ 1,251,300 11,490,800 | \$ | 1,251,300 3,893,700 | \$ 6,455,000 | \$ 775,600 | \$ 366,500 |
|---|-------------------------------|----|------------------------|-----------------|---------------|---------------|
| Commercial commitments: | | | | | | |
| Clinical development | \$ 1,651,200 | \$ | 1,651,200 | \$ _ | \$ _ | \$ _ |
| Manufacturing development | 3,146,300 | | 3,146,300 | _ | _ | _ |
| Total commercial commitments | \$ 4,797,850 | \$ | 4,797,850 | \$ | \$ | \$ |
| | | | | | _ | |
| | | 23 | | | | |

In February 2004, AVANT completed a direct equity placement of 8,965,000 shares of common stock to institutional investors at a price of \$2.75 per share which generated gross proceeds totaling approximately \$24.7 million. Expenses associated with the transaction totaled approximately \$1,602,800.

AVANT believes that cash inflows from existing collaborations, interest income on invested funds and its current cash and cash equivalents will be sufficient to meet estimated working capital requirements and fund operations beyond December 31, 2005. The working capital requirements of AVANT are dependent on several factors including, but not limited to, the costs associated with research and development programs, preclinical and clinical studies and the scope of collaborative arrangements. During the remainder of 2004 and 2005, AVANT may take steps to raise additional capital including, but not limited to, the licensing of technology programs with existing or new collaborative partners, possible business combinations, or the issuance of common stock via private placement and public offering. There can be no assurance that such efforts will be successful.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We own financial instruments that are sensitive to market risk as part of our investment portfolio. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We invest our cash primarily in money market mutual funds and U.S. Government and other investment grade debt securities. These investments are evaluated quarterly to determine the fair value of the portfolio. Our investment portfolio includes only marketable securities with active secondary or resale markets to help insure liquidity. We have implemented policies regarding the amount and credit ratings of investments. Due to the conservative nature of these policies, we do not believe we have material exposure due to market risk. The impact to our financial position and results of operations from likely changes in interest rates is not material.

We do not utilize derivative financial instruments. The carrying amounts reflected in the consolidated balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximates fair value at September 30, 2004 and December 31, 2003 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as of September 30, 2004, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating our disclosure controls and procedures, we and our management recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that they believe that, as of the date of completion of the evaluation, our disclosure controls and procedures were reasonably effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. We will continue to review and document our disclosure controls and procedures on an ongoing basis, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

24

Changes in Internal Control Over Financial Reporting.

There was no significant change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we establish and maintain an adequate internal control structure and procedures for financial reporting and assess on an on-going basis the design and operating effectiveness of our internal control structure and procedures for financial reporting. Our auditors are required to audit both the design and operating effectiveness of our internal controls and management's assessment of the design and the effectiveness of its internal controls. Although based on management's most recent evaluation, there are no known material material weaknesses at this time, it is possible that material weaknesses could be found. If management is unable to remediate any material weaknesses that may arise, management would need to conclude in their assessment that its internal controls over financial reporting were not effective. It is uncertain what impact this would have on our Company.

PART II — OTHER INFORMATION

Item 6. Exhibits

Design/Builder Agreement, dated August 20, 2004 by and between AVANT Immunotherapeutics, Inc. and SPEC Process Engineering & Construction, Inc.

| 31.1 | Certification of President and Chief Executive Officer |
|------|--|
| 31.2 | Certification of Senior Vice President and Chief Financial Officer |
| 32.1 | Section 1350 Certifications |
| | 25 |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AVANT IMMUNOTHERAPEUTICS, INC.

BY:

Dated: November 8, 2004

/s/ Una S. Ryan
Una S. Ryan, Ph. D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 8, 2004 /s/ Avery W. Catlin

Avery W. Catlin
Senior Vice President, Treasurer
and Chief Financial Officer
(Principal Financial and
Accounting Officer)

26

EXHIBIT INDEX

| Exhibit No. | Description |
|-------------|---|
| 10.1 | Design/Builder Agreement, dated August 20, 2004 by and between AVANT Immunotherapeutics, Inc. and SPEC Process Engineering & Construction, Inc. |
| 31.1 | Certification of President and Chief Executive Officer |
| 31.2 | Certification of Senior Vice President and Chief Financial Officer |
| 32.1 | Section 1350 Certifications |
| | 27 |

Supplemental Conditions of the Standard Form of Agreement Between Owner and Design/Builder between AVANT Immunotherapeutics, Inc. ("Owner") and SPEC Process Engineering & Construction, Inc. ("Design/Builder")

These Supplemental Conditions of the Standard Form of Agreement Between Owner and Design/Builder (these "Supplemental Conditions") supplement and modify the Standard Form of Agreement Between Owner and Design/Builder, Part 2 Agreement, 1996 edition of AIA Document A191, as modified, which is being entered into by Owner and Design/Builder simultaneously with the execution and delivery of these Supplemental Conditions (the "Agreement"). In the event of any conflict between the Agreement and these Supplemental Conditions, the terms of these Supplemental Conditions shall control. Capitalized terms used in these Supplemental Conditions without definition shall have the meanings ascribed to them in the Agreement.

1. Project Program. The Owner and the Design/Builder have developed the program for the Project (the "Project Program") described in Exhibit 4. The Project Program sets forth the mutual understanding of the Owner and the Design/Builder of the Owner's needs and requirements for the Project. In establishing the Project Program, the Owner and the Design/Builder have discussed and considered, without limitation: (a) the Owner's overall objectives, limitations and criteria for the Project; (b) human, vehicular and material flow patterns that characterize the services that the Owner will provide; (c) tasks performed by each operating unit that will be accommodated at the Project, each unit's overall space requirements and how each unit must work with other operating units; (d) the number types of personnel assigned to each unit, and the amount and type of space required by each; (e) any special processes conducted by the Owner, including flow diagrams, personnel requirements and the relationship of each process to other processes that will be conducted at the Project; (f) all equipment and systems that will be located in the Project, including the size and dimensions of each item of equipment, and the relationship of each item of equipment to other equipment, processes and personnel; (g) overall utility requirements for the Project; (h) special utility requirements for equipment and processes; (i) security criteria; (j) requirements for future expansion or alteration; (k) existing utility characteristics and utility availability. The Guaranteed Maximum Price (as hereinafter defined) and Construction Schedule (as hereinafter defined) have been established based on the Project Program.

2. <u>Execution, Correlation and Intent.</u>

- (a) The Drawings and Specifications prepared by or on behalf of Design/Builder will be based upon, and comply with, the Project Program. Although the Owner will be provided with copies of progress drafts of the Drawings and Specifications at appropriate intervals as such documents are developed, and may be asked to approve the same: (i) the Design/Builder shall be responsible to ensure that the Drawings and Specifications comply with the Project Program and the provisions of the Contract Documents; and (ii) should the Owner request any change in the Drawings and Specifications which is inconsistent with the Project Program, such request for a change will be handled in accordance with Article 8 of the Agreement.
- (b) In the performance of its services hereunder, Design/Builder shall make a diligent investigation of all laws, statutes, ordinances, building codes, rules and regulations

applicable to the design, construction and intended use of the Project ("Laws"), including, without limitation, requirements of the Americans With Disabilities Act, as interpreted and applied by governmental officials with jurisdiction over the design and construction of the Project, and any energy efficiency requirements, and shall prepare all Construction Documents and perform the Work in compliance with all Laws, to the extent in force and effect at the time Design/Builder renders such services.

- (c) All manufactured articles, materials, and equipment shall be applied, installed, connected, erected, used and cleaned in accordance with the manufacturer's written or printed directions and instructions unless otherwise indicated.
- (d) Where no explicit quality or standards for materials or workmanship are established for Work, such Work is to be consistent with the quality of the surrounding Work and of the construction of the Project generally.
- 3. <u>Third Party Beneficiary.</u> Supplementing the provisions of Paragraphs 1.2.3 and 3.1.1 of the Agreement, the Owner shall be an intended third party beneficiary of the services performed by the Architect, the Subcontractors, and all parties providing labor, materials or services for the Project.
- 4. Ownership and Use of Design Documents. Article 3 of the Agreement is hereby superseded in its entirety by the provisions of this Section. All Plans and Specifications, and any design or creative concepts contained therein, and any other design materials submitted, created, developed, supplied or generated in connection with the Project and this Agreement by or on behalf of the Design/Builder (the "Covered Documents") shall be considered "works made for hire" under 17 U.S.C. §101, and shall be and remain the sole, exclusive and complete property of Owner at all times, and Owner shall own all rights, copyrights, or other intellectual property rights there may be with respect to the Covered Documents. Design/Builder shall deliver copies, including reproducible copies and copies of computer disks or other computer memory storage devices, of the Covered Documents to Owner for information, reference and use. The Design/Builder hereby agrees to execute and furnish, as necessary, any assignment or other document that may be necessary to perfect, confirm or maintain the Owner's ownership of all intellectual property rights in the Covered Documents. The Design/Builder shall not use the Covered Documents for any purpose not relating to the Project without the Owner's prior written consent. Prior to final payment or at any other time requested by the Owner, the Design/Builder shall cause the any separate architect, engineer or other party providing design services to deliver instruments in form and substance satisfactory to the Owner confirming Owner's ownership of the Covered Documents. Submission or distribution of the Covered Documents to meet official regulatory requirements or for similar purposes in connection with the Project is not to be construed as publication in derogation of the reserved rights of the Owner. The Design/Builder shall not be responsible for Owner's use without the participation of the Design/Builder on projects other than the Project; and Owner shall indemnify and hold harmless the Design/Buil
- 5. <u>Construction Documents</u>. Supplementing the provisions of Paragraph 3.2.3, each iteration of the Construction Documents submitted to the Owner for approval shall show by

clouding all changes from the previous versions (including changes from the preliminary design documents prepared prior to the execution of the Agreement), and shall be accompanied by a statement from the Design/Builder delineating with reasonable specificity the nature and extent of all such changes. The Owner will endeavor to complete its review of each progress draft of the Construction Documents submitted to the Owner within ten (10) working days following Owner's receipt. If the Owner requests any changes to a progress draft of the Construction Documents after the expiration of such ten (10) working day period, the Design/Builder may be entitled to an extension of the time for performing the Work (subject to Section 9 hereof) unless the change is required to (a) conform such Construction Documents to the Project Program or Laws, (b) make the Construction Documents consistent with any previous draft of the Construction Documents reviewed and accepted by the Owner, (c) fully and properly implement or correct any items which were previously the subject of any Owner comments or otherwise supposed to be included the Construction Documents, or (d) correct any errors, omissions or internal inconsistencies contained within the Contract Documents.

- 6. <u>Licenses, Permits and Approvals</u>. Supplementing the provisions of Paragraph 3.2.10, the Design/Builder shall obtain as a Basic Service within the Guaranteed Maximum Price all designated or required governmental inspections and all required certificates of occupancy and operating permits for machinery and equipment included in the Project.
- 7. Record Documents. Notwithstanding anything to the contrary (including, without limitation, the provisions of Paragraph 3.3.6 of the Agreement), the Design/Builder shall prepare and deliver to Owner prior to final payment reproducible sets of the Construction Documents, in print and electronic format acceptable to the Owner, showing (a) deviations from the Construction Documents made during construction, (ii) details in the Work not previously shown, (iii) changes to existing conditions or existing conditions found to differ from those shown on the Construction Documents, (iv) the actual installed position of cable, equipment, piping conduits, switches, electric fixtures, circuiting, access panels, openings, stub-outs and similar items, and (v) such other information as the Owner may reasonably request. This shall be done as a Basic Service within the Guaranteed Maximum Price (the "Record Documents").
- 8. <u>Additional Services</u>. Notwithstanding anything to the contrary, any services which are required of Design/Builder and its consultants due to errors or omissions of Design/Builder or its subcontractors or consultants (including the Architect) shall not be considered Additional Services and shall not entitle Design/Builder and its consultants to compensation.

9. <u>Time</u>.

(a) The Design/Builder shall perform and deliver the Work in accordance with the schedule for the Work attached hereto as Exhibit 1 (as amended from time to time with the written approval of the Owner or otherwise in accordance with the Contract Documents, the "Construction Schedule"). The Construction Schedule includes dates that are critical in ensuring the timely and orderly completion of the Work in accordance with the Contract Documents. In the event that the performance of the Work has not progressed or reached the level of completion required by the Construction Schedule, Owner shall have the right to compel Design/Builder to take corrective measures to expedite the progress of the Work, including, without limitation, (i) working additional shifts or overtime and/or (ii) supplying additional manpower, equipment

3

and facilities (collectively, "Extraordinary Measures"). Such Extraordinary Measures shall be performed at no additional cost to the Owner and shall continue until the progress of the Work complies with the level of completion required by the Construction Schedule. The Design/Builder shall not be entitled to any adjustment in the Contract Sum in connection with Extraordinary Measures required by the Owner.

- (b) The Design/Builder acknowledges and agrees that (1) no adjustments to the time for performing the Work shall be made unless the events described in Paragraph 4.5 of the Agreement shall have the effect of actually delaying completion of components of the Work on the critical path indicated in the Construction Schedule and (2) adjustments to the time for performing the Work will be permitted in connection with any such delay only to the extent such delay (i) is not caused, or could not have been avoided, by the Design/Builder or anyone for whom the Design/Builder is responsible, (ii) could not be limited or avoided by the Design/Builder's timely notice to the Owner of the delay and (iii) has no concurrent or contributing cause for which the Design/Builder would not be entitled to an extension of the time for performing the Work. Notwithstanding anything to the contrary (including, without limitation, the provisions of Paragraph 4.5 of the Agreement), the Design/Builder shall not be entitled to any extension of the time for performing the Work or any increase in the Contract Sum on account of any labor action directed at the Design/Builder, any subcontractor, any lower tier subcontractor, any supplier or any other party for whom the Design/Builder is responsible.
 - 10. <u>Progress Payments</u>. The provisions of this Section modify and supplement the provisions of Article 5 of the Agreement
- (a) Applications for Payment shall be submitted on a form approved by the Owner. Each Application for Payment shall cover a period of one calendar month. In addition to other required items, each Application for Payment shall be accompanied by the following, all in form and substance satisfactory to the Owner:
 - (i) A certified report from the Design/Builder (in form and substance satisfactory to the Owner) showing all suppliers who have provided supplies and/or materials to the Project and Subcontractors with whom the Design/Builder has entered into subcontracts, the amounts of such subcontracts, the amount requested for any Subcontractor in the Application for Payment and the amount to be paid to the Design/Builder from such progress payment;
 - (ii) A duly executed Partial Waiver and Subordination of Lien from the Design/Builder in the form required by M.G.L. c. 254, § 32, together with the Owner's Supplement to Partial Waiver and Subordination of Lien, each in the form attached as Exhibit 2, completed in a manner satisfactory to the Owner;
 - (iii) A duly executed Payment Acknowledgment and Lien Waiver, in the form attached hereto as Exhibit 3, from each Subcontractor (and, to the extent requested by the Owner, each lower tier subcontractor and supplier) for whom payment was made under previous Applications for Payment; and
 - (iv) Such other information, documentation and materials as the Owner may reasonably require.

- (b) Provided an Application for Payment properly prepared and accompanied by all required lien waivers and supporting materials is received by the Owner not later than the 5th day of a month for the immediately preceding calendar month, the Owner shall make payment to the Design/Builder not later than the 5th day of the following month. If an Application for Payment properly prepared and accompanied by all required lien waivers and supporting materials is received by the Owner after the application date fixed above, payment shall be made by the Owner not later than the 30th day following the date when such materials were received.
- (c) Retainage will not be withheld from progress payments except as set forth in this paragraph. No further payments shall be made to Design/Builder after the Owner has paid ninety percent (90%) of the Contract Sum (as reasonably estimated by the Owner) to Design/Builder. Upon achievement of Substantial Completion of the Work, the Owner shall release to the Design/Builder all retainage except an amount equal to the sum of (i) five percent (5%) of the Design/Builder's Fee plus (ii) two hundred percent (200%) of the estimated cost to correct or complete incorrect or incomplete Work as shown on the Punchlist (as hereinafter defined). The Owner shall thereafter make payments monthly for corrected and/or completed Punchlist items as such Punchlist items are corrected and/or completed. Final payment of the balance of such withheld sum shall be made upon correction or completion of all incomplete or nonconforming Work.

11. <u>Completion of the Work</u>.

- (a) Substantial Completion of the Work shall be achieved when (1) all Project systems included in the Work are operational as designed and specified, (2) all designated or required municipal governmental inspections (*e.g.*, building department, etc.) have been successfully completed, and temporary or permanent certificates of occupancy have been obtained (allowing unrestricted use and occupancy by the Owner as intended), and (3) all of the other conditions precedent to Substantial Completion of the Work set forth on Schedule E have been satisfied. When the Design/Builder believes that Substantial Completion of the Work has been achieved, the Design/Builder shall submit to the Owner a list of items to be completed or corrected together with the Design/Builder's proposed estimated value of completing or correcting such item (as approved or the Owner, the "Punchlist"). Upon receipt of the Design/Builder's list, the Owner will make an inspection to determine whether (i) Substantial Completion of the Work has been achieved and/or (ii) whether the proposed Punchlist submitted by Design/Builder is correct and complete. The Owner shall have the right to modify and/or supplement the list of items on the proposed Punchlist submitted by Design/Builder and to modify or, for items added by the Owner, establish the estimated value of completing or correcting such items. The failure to include any items on the Punchlist does not alter the responsibility of the Design/Builder to complete all Work in accordance with the Contract Documents.
- (b) Supplementing the provisions of Paragraph 5.2 of the Agreement, final completion of the Work shall not be deemed to have occurred, and final payment shall not become due and payable unless and until, all Work has been fully completed and Design/Builder has delivered to Owner, and Owner has approved, the following items: (i) conditional final lien waivers from Design/Builder and all Subcontractors in form and substance satisfactory to the Owner demonstrating receipt by such parties of all prior payments and confirming that the only

5

outstanding amounts payable with respect to the Work are amounts to be paid out of the final payment; (ii) the Record Documents; (iii) all special warranties and binders containing information on equipment and controls that are part of the Work; and (iv) to the extent not previously delivered, final and unconditional certificates of occupancy for the Work.

- 12. <u>Hazardous Materials</u>. In the event the Design/Builder encounters at the Project site material reasonably believed to be hazardous under state or federal law which has not been rendered harmless, the Design/Builder shall report the condition to the Owner in writing. The Work in the affected area shall not thereafter be resumed except by written agreement of the Owner and Design/Builder if hazardous or contaminated under state or federal law and has not been rendered harmless. The Work in the affected area shall be resumed in the absence of material defined as hazardous or contaminated under state or federal law or when it has been rendered harmless. The Design/Builder shall not be required pursuant to Article 8 of the Agreement to perform without consent any Work relating to material defined as hazardous or contaminated under state or federal law. If, without negligence on the part of the Design/Builder or anyone for whom the Design/Builder is responsible, the Design/Builder is held liable for the cost of remediation of a hazardous material or substance outside the scope of the Work solely by reason of performing Work as required by the Contract Documents, the Owner shall indemnify the Design/Builder for all cost and expense thereby incurred.
 - 13. <u>Insurance</u>. The provisions of this Section modify and supplement Article 7 of the Agreement.
- (a) <u>Design/Builder's Insurance</u>. The Design/Builder shall procure and maintain, at the Design/Builder's expense, the following insurance coverages, which insurance shall be placed with insurance companies rated at least A/VI or better in Best's Key Rating Guide. Each policy shall include an endorsement requiring that the insurance company give written notice to Owner at least thirty (30) days prior to the modification, cancellation, non-renewal or reduction in the coverage limits of such policy:
 - (i) Workers' compensation insurance in statutory amounts and employer's liability insurance in the amount of \$500,000;
 - (ii) Motor vehicle insurance covering owned, non-owned and hired vehicles for personal injury in the amount of \$1,000,000 combined single limit for bodily injury and for property damage;
 - (iii) Commercial general liability coverage for bodily injury, personal injury and property damage in the amount of \$1,000,000 bodily injury per occurrence, \$1,000,000 property damage per occurrence and \$5,000,000 aggregate limit;
 - (iv) Professional liability coverage for all professional services relating to the Project in the minimum amount of \$2,000,000; and
 - (v) Umbrella Liability Coverage over Commercial General Liability and Motor Vehicle Insurance in the amount of \$5,000,000.

The liability policies shall include a contractual liability endorsement covering the indemnification obligations under the Contract Documents. The "other insurance" clause shall be deleted from each policy of insurance carried by the Design/Builder so as to make it clear that the coverage of such policy is primary and any coverage under any policy or policies of insurance held by the Owner or any other additional insured is secondary. Each policy of insurance carried by the Design/Builder shall be endorsed to provide a separate general aggregate limit for the Work performed under this Contract, and will, by its terms, specifically cover the entire term of the Contract Documents. All of the insurance required to maintained by Design/Builder shall be written on an occurrence basis, except that professional liability and umbrella liability can be written on a claims made basis provided that such coverages are maintained for six years following final payment. The Owner, the Landlord, any lender(s) and such other persons designated by the Owner from time to time shall be named as additional insureds on all insurance policies required hereunder except workers' compensation and professional liability policies. The Design/Builder shall, upon demand, provide the Owner with proof that the insurance requirements have been met, which shall be in the form of certificates of insurance (or, at the Owner's request, insurance policies) reasonably acceptable to the Owner. Renewal certificates for all policies that expire during the term of the Contract Documents must also be provided at least thirty (30) days prior to each policy's respective expiration. Nothing in this clause, or any failure of Design/Builder to secure required coverages or otherwise comply with the insurance provisions of the Contract Documents, shall modify or limit the Design/Builder's liability or other obligations under the Contract Documents.

(b) Owner's Insurance. Notwithstanding anything to the contrary in the Contract Documents: (a) any property insurance maintained by the Owner or the Landlord shall not be required to cover portions of the Work stored off site or portions of the Work in transit; (b) the Owner shall have the sole right to adjust and settle claims with its property insurers and shall have no obligation to post any bond for performance of its duties; (c) although the Owner shall be required to act in good faith in adjusting any claims with its property insurers and thereafter applying any insurance proceeds received from its property insurers, the Owner shall not be a fiduciary of the Design/Builder or any Subcontractor; and (d) any liability insurance maintained by the Owner is and shall be secondary to and excess of any insurance maintained by the Design/Builder, the Architect, any subcontractor or any other party for whom the Design/Builder is responsible.

14. <u>Changes in the Work</u>.

- (a) No change in the Work shall proceed and no claim for additional monies or additional time for any extra Work will be valid unless such Work is done pursuant to a written Change Order or Construction Change Directive. Notwithstanding anything to the contrary, the maximum allowable percentages for fee and so-called "general conditions" and "general requirements" items to Design/Builder on proposals for an increase in the Contract Sum shall not exceed sixteen percent (16%) of the net increase in the direct Cost of the Work (*i.e.*, the Cost of the Work excluding Design/Builder's fee and so-called "general conditions" and "general requirements" items).
- (b) The Owner will designate individuals (each, an "Owner Representative") who shall be authorized to approve or direct changes in the Work. The initial Owner

7

Representatives are Mary Nicholson. The Owner may change, or name additional, Owner Representatives from time to time by written notice to Design/Builder.

15. <u>Claims and Disputes</u>.

- (a) In the event of any mediation, arbitration or legal proceeding between the Owner and any third party arising out of or relating to the Project, the Design/Builder agrees that (i) the Owner may join the Design/Builder in any such proceedings and that the Owner may consolidate any such proceedings with any proceeding between the Design/Builder and the Owner under the Contract Documents, and (ii) the Owner may make persons other than the Owner and the Design/Builder parties to any mediation, arbitration or legal proceeding hereunder with respect to any claim, dispute or other matter in question arising out the Project.
- (b) The provisions of Paragraph 11.4 of the Agreement shall not limit the time within which the Owner may assert any claim against the Design/Builder alleging a failure to comply with the Contract Documents or any defective or nonconforming Work.
- 16. <u>Indemnification</u>. The obligations of the Design/Builder to indemnify and hold harmless under Paragraph 11.5 of the Agreement shall: (a) extend to the Landlord, any lender(s) and the partners, officers, directors, trustees and employees of the Owner, the Landlord and any lender(s); and (b) include, to the fullest extent permitted by law, any claims, damages, losses or expenses in any way arising or alleged to be arising from the design or performance of the Work or the failure of the Design/Builder, the Design/Builder's Subcontractors, lower level subcontractors and employees or agents of any of them to design or perform the Work in accordance with applicable Laws.

17. <u>Compensation</u>.

- (a) <u>Contract Sum.</u> For Design/Builder's performance of the Work, Owner shall pay Design/Builder an amount (the "Contract Sum") consisting of the Cost of the Work (as hereinafter defined) and the Design/Builder's Fee (as hereinafter defined); provided, however, that the Contract Sum shall in no event exceed One Million Nine Hundred Seventeen Thousand Seven Hundred Two Dollars (\$1,917,702) (as adjusted by Change Order pursuant the Contract Documents, the "Guaranteed Maximum Price").
 - (i) <u>Cost of the Work</u>. The term "Cost of the Work" shall mean the costs set forth on Schedule A attached hereto which are actually and necessarily incurred by Design/Builder in the proper performance of the Work. Such costs shall be at rates not higher than those customarily paid at the place of the Project except with prior consent of Owner. ..
 - (ii) <u>Design/Builder's Fee</u>. Design/Builder's fee for all services hereunder ("Design/Builder's Fee") shall be the stipulated lump sum amount of One Hundred Eight Thousand Five Hundred Forty-Nine Dollars (\$108,549).
 - (iii) <u>Savings</u>. All "Guaranteed Maximum Price Savings" (as such term is defined below), if any, shall accrue to the Owner. As of the date of final completion of the Work the amount, if any, by which (x) exceeds (y) shall be considered the

"Guaranteed Maximum Price Savings," where (x) is the Guaranteed Maximum Price and (y) is the sum of the actual Cost of the Work and the actual Design/Builder's Fee.

- Competitive Bids. Except as otherwise agreed in writing by the Owner, all labor, materials and equipment (whether rented or purchased) for each portion of the Work with a cost (together with all other items to be provided by the proposed subcontractor or supplier) of Ten Thousand Dollars (\$10,000) or more shall be obtained on the basis of competitive bids in accordance with this paragraph. Design/Builder shall provide the Owner with a list of proposed bidders for each portion of the Work who have been selected by Design/Builder for their ability to perform the applicable Work. The Owner may, but shall have no obligation to, review and approve the Design/Builder's list of proposed bidders prior to the Design/Builder's solicitation of bids. Design/Builder shall request bids from at least three (3) prospective qualified subcontractors or suppliers from such list for each portion of the Work that Design/Builder does not intend to perform with Design/Builder's own forces or through an affiliate of Design/Builder. For any portion of the Work that Design/Builder intends to perform with Design/Builder's own forces or through an affiliate, Design/Builder shall (i) request bids from at least two (2) prospective qualified subcontractors or suppliers unaffiliated with Design/Builder from the list and (ii) submit, or cause its affiliate to submit, a bid for the Work to Owner at least one (1) business day prior to receipt of bids from the unaffiliated prospective subcontractors or suppliers. Following receipt of all bids for a portion of the Work, Design/Builder shall equalize (based on scope of Work and bid responses) and summarize the bids received and make recommendations to Owner as to which bids should be accepted. Design/Builder, with the Owner's consent, shall then determine which bids will be accepted. Work by a Design/Builder or affiliate of Design/Builder shall be permitted only if (1) Owner consents thereto in writing after full disclosure in writing by the Design/Builder to the Owner of the affiliation or relationship and (2) Owner approves in writing any subcontract, contract, purchase order, agreement or other arrangement in form and substance. Unless the Owner otherwise approves in writing, the lowest qualified bidder (that is a bidder who, if selected, is capable of performing the applicable Work without having a negative effect on the outcome of the project or impairing the Design/Builder's ability to meet the requirements of this Agreement) will be selected by Design/Builder; however, the Design/Builder may elect to use a bidder other than the low bidder without the written approval of the Owner if the selected bidder is within 2.5% of the cost of the low bidder (but any such selection shall not increase the Guaranteed Maximum Price). If the Owner without reasonable justification requires the Design/Builder to select a bidder other than the lowest priced qualified bidder recommended by Design/Builder, and the bid price of the bidder required by Owner is higher than the bid price of the lowest priced qualified bidder recommended by Design/Builder, the Guaranteed Maximum Price shall be increased by the difference between the bid price of the bidder required by Owner and the bid price of the lowest priced qualified bidder recommended by Design/Builder, which adjustment to the Guaranteed Maximum Price shall be implemented by Change Order prior to commencement of the applicable subcontractor's Work.
- (c) <u>Discounts, Rebates and Refunds</u>. All discounts, rebates or refunds in connection with the Work shall be credited against the Cost of the Work.
- (d) <u>Books and Records</u>. Design/Builder shall keep full and detailed accounts as necessary for proper financial management of the Project. Owner and its representatives shall

9

at all reasonable times be afforded access to all records, books, correspondence, instructions, drawings, receipts, vouchers, memoranda and similar data of Design/Builder and any and all of its consultants and subcontractors relating to the Agreement and performance of the Work, and may make copies of such items. Design/Builder and all of its consultants and subcontractors shall preserve all such records for a period of at least three years after the final payment or longer where required by law. Design/Builder shall cause all of its consultants and subcontractors to comply with the provisions of this paragraph. If any review by Owner reveals an overpayment by Owner, Design/Builder shall pay to the Owner the amount of such overpayment within ten (10) days of Owner's demand.

18. <u>Schedule of Values; Allowances</u>.

- (a) The initial schedule of values allocating the Guaranteed Maximum Price among the various components of the Work prepared by the Design/Builder and approved by the Owner is attached hereto as Schedule C (as amended from time to time with the approval of the Owner, the "Schedule of Values"). The Schedule of Values shall be updated by the Design/Builder as frequently as necessary to reflect changes as the Work proceeds.
- (b) The Guaranteed Maximum Price includes allowances for the items, and in the amounts, set forth on Schedule D attached hereto and made a part hereof. The Guaranteed Maximum Price shall be increased or decreased, as applicable, by the difference between (i) the amount of each allowance then listed on Schedule D and (ii) the actual out-of-pocket cost to the Design/Builder of providing any of the allowance items.
- 19. <u>Liens</u>. In the event that any Subcontractor, supplier or other party for whom the Design/Builder is responsible establishes a lien against the Project and/or the Project site, the Design/Builder shall, within five (5) days following the request of the Owner, obtain for the Owner's benefit and at no cost to the Owner, cause such lien to be discharged (by filing a lien discharge bond from a surety and in a form acceptable to the Owner or otherwise). If the Design/Builder fails to obtain a cause such lien to be discharged within such five (5) day period, the Owner shall have the right to (a) withhold succeeding progress payments or any other sums payable to the Design/Builder and/or (b) have such lien discharged (by bonding, by making payment to the lienor, or otherwise) at the Design/Builder's cost and expense. The Owner may either apply amounts so withheld to discharging such lien(s) or may retain such amounts until such lien(s) are discharged or released by the Design/Builder or the lienor and shall thereafter credit to the Design/Builder any amounts remaining after payment of the fees and expenses the Owner incurs in connection with such lien(s). The Design/Builder agrees to indemnify and hold harmless the Owner from all costs and expenses incurred by the Owner in connection with defending or discharging such lien(s).
- 20. <u>Non-Recourse</u>. No partner, member, shareholder, director, officer, agent or employee of the Owner or any of the foregoing shall have any personal liability arising out of the Contract Documents or the Project.
- 21. <u>Key Personnel</u>. The members of the Design/Builder's and Architect's staff assigned to and primarily responsible for supervising and/or performing the Work shall be the following persons:

| Person | Position |
|--------------|------------------------|
| Steve Murray | Project Manager |
| Steve Savage | Project Superintendent |
| Anne Myers | Project Architect |

Such key members of the Design/Builder's staff shall not be changed without the written consent of the Owner, unless such person becomes unable to perform his or her duties due to death, disability or termination of employment, or unless the Owner requests removal. If a key member is no longer capable of performing in the capacity described in the attached exhibit, or is removed by the Owner, the Owner and the Design/Builder shall agree on a mutually acceptable substitute.

- 22. Protection From Water Damage. In performing the Work, the Design/Builder shall exercise diligent efforts to protect the Project and to cause all materials, supplies, systems and equipment which are delivered to the Project site from exposure to, and damage from, water. Without limiting the generality of the foregoing, the Design/Builder shall (a) cause all materials, supplies, systems and equipment which are delivered to the Project site to be stored in a safe and secure location, packaged in a watertight manner where possible, and stored in a manner which protects such items from inclement weather, the elements (including, without limitation, rain, snow and water damage) and other damage until such items are incorporated into the Work, and (b) ensure that all plumbing components and exterior elements included within the Work are constructed and installed in accordance with the Contract Documents so as not to allow water leaks or penetration. In addition to (and not in limitation of) the indemnification obligations of Design/Builder set forth in Paragraph 11.5 of the Agreement, Design/Builder shall indemnify and hold harmless the indemnified parties to the fullest extent permitted by law from all claims, liabilities and losses arising out of or resulting from the failure of the Design/Builder (or any subcontractor of any tier) to comply with the provisions of this paragraph. The foregoing indemnification shall include, without limitation, any claim, liability of loss attributable to (i) bodily injury, sickness, disease or death arising out of or relating to, and (ii) the costs of any abatement, clean-up, removal and disposal (to the satisfaction of Owner) of, any mold, fungal growth, spores or the like which occurs at the Project site as a result of any failure by Design/Builder (or any subcontractor of any tier) to comply with the provisions of this paragraph.
- 23. <u>Termination by the Owner for Convenience</u>. Subparagraph 12.1.1 of the Agreement is hereby deleted in its entirety and superseded by this Section. The Owner may terminate the Design/Builder's services in whole or in part for the Owner's convenience without cause. In case of termination for the Owner's convenience without cause, the Design/Builder shall be entitled to receive payment for Work properly executed in accordance with the Contract Documents (the basis for such payment shall be as provided in the Agreement and these Supplemental Conditions) and for reasonable demobilization and cancellation charges incurred by the Design/Builder directly related to the termination of the Work (including reasonable amounts necessary to terminate agreements with Subcontractors and suppliers). The Design/Builder shall not be entitled (nor shall any Subcontractor be entitled) to consequential or incidental damages, including, but not limited to, damages for loss of anticipated profits on Work not performed, on account of any termination for the Owner's convenience."

11

- Financing for the Project. Subparagraph 2.10 of the Agreement is hereby deleted in its entirety. The Design/Builder acknowledges that the Owner may finance the work with funds provided and/or administered by one or more construction lenders (each, a "Lender"). The Design/Builder agrees to comply with the requirements of each Lender which bear upon the performance of the Work. The Design/Builder shall also: (a) make the site of the Work available at reasonable times for inspection by the Lender or the Lender's representatives; (b) consent to and execute all documents reasonably requested by the Owner or any Lender in connection with the assignment of the Contract to any Lender for collateral purposes and/or the disbursement of funds by any Lender; (c) promptly furnish the Owner with information, documents, materials and/or certificates that the Owner may reasonably request from time to time in order to comply with the requirements of the Lender; and (d) otherwise comply with all requirements of any Lender to the extent applicable to the performance of the Work.
- Special Provisions Regarding Lease. Notwithstanding anything to the contrary, the Design/Builder acknowledges and agrees that: (a) the Work is to be performed in premises leased from Massachusetts Development Finance Agency ("Landlord"); (b) the Design/Builder shall make the site of the Work available at reasonable times for inspection by Landlord or Landlord's representatives; (c) all or a portion of the Contract Sum shall be paid with funds provided by Landlord; (d) the Design/Builder shall comply with any requirements, rules or procedures imposed by Landlord and agreed to by the Owner which relate to the design and/or performance of the Work or payment for the Work within the Guaranteed Maximum Price (including all charges imposed by Landlord thereunder); (e) the Landlord, and not the Owner, shall be providing property insurance for the Project and the Project site, which property insurance shall include only the coverages and limits normally carried by the Landlord; (f) the Landlord shall be an indemnified party and shall be named as an additional insured to the same extent as Owner under the Contract Documents; and (g) the Design/Builder's architect or engineer shall certify to Owner and Landlord that all components of the Work, once installed, will be compatible with the building's plumbing, electrical and mechanical systems.
- 26. <u>Confidentiality</u>. Design/Builder shall maintain, and cause all of its subcontractors to maintain, the confidentiality of all information about the Owner and the Project that would reasonably be considered confidential (including, without limitation, technical information or specifications regarding the Project and/or the Owner's proprietary processes and procedures), unless withholding such information would violate the law or prevent Design/Builder from establishing a claim or defense in an adjudicatory proceeding.
- 27. <u>Building in Use</u>. Design/Builder recognizes that the Project may involve working in a facility which will be in use during the period of construction, and Design/Builder shall cooperate with the Owner and perform its Work hereunder in such a manner and at such times so as to (a) protect persons and property in the facility and (b) minimize interference with the present operation of the facility. Design/Builder acknowledges that it incorporated into it's Contract budget that the facility and surrounding areas are open to the public, and Design/Builder agrees to make no claims for additional costs or damages associated with any inefficiencies caused by the normal building operations. Neither shall the Owner be required to make any adjustment in the Contract Time for the Design/Builder for any delays associated with normal building operations. The Design/Builder may make claims for additional costs or

| 28. <u>Counterparts</u> . These Supplemental Conditions may be executed in a binding on the parties hereto. | one or more counterparts, each of which shall be deemed an original | | | | | |
|--|---|--|--|--|--|--|
| [Signatures on Followin | g Page(s)] | | | | | |
| 13 | | | | | | |
| IN WITNESS WHEREOF, the Owner and the Design/Builder have entered into this Rider as of the date first set forth in the Agreement. | | | | | | |
| | AVANT IMMUNOTHERAPEUTICS, INC. | | | | | |
| | By:Name:Title: SPEC PROCESS ENGINEERING & | | | | | |
| | CONSTRUCTION, INC. | | | | | |
| | By: Name: Title: | | | | | |
| 14 | | | | | | |
| | | | | | | |

CERTIFICATION

I, Una S. Ryan, certify that:

- 1. I have reviewed this report on Form 10-Q of AVANT Immunotherapeutics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2004

By: /s/ Una S. Ryan

Name: Una S. Ryan, Ph.D.

Title: President and Chief Executive Officer

CERTIFICATION

I, Avery W. Catlin, certify that:

- 1. I have reviewed this report on Form 10-Q of AVANT Immunotherapeutics, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2004 By: /s/ Avery W. Catlin

Name: Avery W. Catlin
Title: Senior Vice President and
Chief Financial Officer

The undersigned officers of AVANT Immunotherapeutics, Inc. (the "Company") hereby certify to our knowledge that the Company's quarterly report on Form 10-Q to which this certification is attached (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2004 By: /s/ Una S. Ryan

Date: November 8, 2004

Name: Una S. Ryan, Ph.D.

Title: President and Chief Executive Officer

By: /s/ Avery W. Catlin

Name: Avery W. Catlin

Title: Senior Vice President and Chief Financial Officer