

---

---

**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, 2003

OR

**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**  
(State of Incorporation)

**No. 13-3191702**  
(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 .

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

As of November 4, 2003, 64,706,069 shares of common stock, \$.001 par value per share, were outstanding.

---

---

---

AVANT IMMUNOTHERAPEUTICS, INC.  
FORM 10-Q  
Quarter Ended September 30, 2003  
Table of Contents

**Part I — Financial Information**

[Consolidated Balance Sheet at September 30, 2003 and December 31, 2002](#)

[Consolidated Statement of Operations for the Three Months Ended  
September 30, 2003 and 2002](#)

[Consolidated Statement of Operations for the Nine Months Ended  
September 30, 2003 and 2002](#)

[Consolidated Statement of Cash Flows for the Nine Months Ended  
September 30, 2003 and 2002](#)

[Notes to Consolidated Financial Statements](#)

[Management's Discussion and Analysis of Financial Condition and Results of Operations](#)

[Item 4. Controls and Procedures](#)

**Part II — Other Information**

[Item 6. Exhibits and Reports on Form 8-K](#)

[\(a\) Exhibits](#)

[\(b\) Reports on Form 8-K](#)

[Signatures](#)

Certifications

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

**AVANT IMMUNOTHERAPEUTICS, INC.**  
**CONSOLIDATED BALANCE SHEET**  
**September 30, 2003 and December 31, 2002**  
**(Unaudited)**

	<u>September 30,</u> <u>2003</u>	<u>December 31,</u> <u>2002</u>
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$ 23,498,400	\$ 25,070,700
Accounts Receivable	568,500	230,900
Prepaid Expenses and Other Current Assets	714,900	558,400
Total Current Assets	<u>24,781,800</u>	<u>25,860,000</u>
Property and Equipment, Net	972,900	1,119,500
Intangible and Other Assets	8,380,800	7,217,400
Goodwill	1,036,300	1,036,300
Total Assets	<u>\$ 35,171,800</u>	<u>\$ 35,233,200</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$ 259,100	\$ 836,000
Accrued Expenses	2,396,200	2,098,900
Current Portion Deferred Revenue	510,200	497,700
Total Current Liabilities	<u>3,165,500</u>	<u>3,432,600</u>
Long-Term Deferred Revenue	82,900	456,200
Stockholders' Equity:		
Common Stock, \$.001 Par Value; 100,000,000 Shares Authorized; 64,926,400 Issued and 64,706,100		
Outstanding at September 30, 2003 and 60,464,900 Issued and 60,332,300 Outstanding at December 31, 2002	64,900	60,500
Additional Paid-In Capital	233,708,000	223,322,900
Less: 220,300 and 132,600 Common Treasury Shares at Cost at September 30, 2003 and December 31, 2002	(227,700)	(136,400)
Deferred Compensation	(1,058,000)	□
Accumulated Deficit	(200,563,800)	(191,902,600)
Total Stockholders' Equity	<u>31,923,400</u>	<u>31,344,400</u>
Total Liabilities and Stockholders' Equity	<u>\$ 35,171,800</u>	<u>\$ 35,233,200</u>

*See accompanying notes to unaudited consolidated financial statements*

**AVANT IMMUNOTHERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENT OF OPERATIONS**  
**For the Three Months Ended September 30, 2003 and 2002**  
**(Unaudited)**

	<u>September 30, 2003</u>	<u>September 30, 2002</u>
<b>REVENUE:</b>		
Product Development and Licensing Agreements	\$ 1,232,900	\$ 4,493,900
Government Contract Revenue	733,700	□
Product Royalties	48,500	□
Product Sales	□	66,500
<b>Total Revenue</b>	<u>2,015,100</u>	<u>4,560,400</u>
<b>OPERATING EXPENSE:</b>		
Research and Development	2,510,100	3,423,200
Selling, General and Administrative	1,423,700	1,325,600
Cost of Product Sales	□	10,300
Amortization of Acquired Intangible Assets	248,800	198,800
<b>Total Operating Expense</b>	<u>4,182,600</u>	<u>4,957,900</u>
<b>Operating Loss</b>	<u>(2,167,500)</u>	<u>(397,500)</u>
Investment Income, Net	51,800	121,300
<b>Net Loss</b>	<u>\$ (2,115,700)</u>	<u>\$ (276,200)</u>
<b>Basic and Diluted Net Loss Per Common Share</b>	<u>\$ (0.03)</u>	<u>\$ (0.01)</u>
<b>Weighted Average Common Shares Outstanding</b>	<u>64,703,000</u>	<u>60,457,800</u>

*See accompanying notes to unaudited consolidated financial statements*

**AVANT IMMUNOTHERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENT OF OPERATIONS**  
**For the Nine Months Ended September 30, 2003 and 2002**  
**(Unaudited)**

	<u>September 30, 2003</u>	<u>September 30, 2002</u>
<b>REVENUE:</b>		
Product Development and Licensing Agreements	\$ 1,620,000	\$ 5,601,600
Government Contract Revenue	2,029,300	□
Product Royalties	125,900	□
Product Sales	□	292,400
<b>Total Revenue</b>	<u>3,775,200</u>	<u>5,894,000</u>
<b>OPERATING EXPENSE:</b>		
Research and Development	7,876,000	11,899,200
Selling, General and Administrative	4,000,100	4,199,000
Cost of Product Sales	□	41,000
Amortization of Acquired Intangible Assets	746,400	596,400
<b>Total Operating Expense</b>	<u>12,622,500</u>	<u>16,735,600</u>
<b>Operating Loss</b>	<u>(8,847,300)</u>	<u>(10,841,600)</u>
Investment Income, Net	186,100	487,500
<b>Net Loss</b>	<u>\$ (8,661,200)</u>	<u>\$ (10,354,100)</u>
<b>Basic and Diluted Net Loss Per Common Share</b>	<u>\$ (0.14)</u>	<u>\$ (0.17)</u>
<b>Weighted Average Common Shares Outstanding</b>	<u>61,773,500</u>	<u>60,458,500</u>

*See accompanying notes to unaudited consolidated financial statements*

**AVANT IMMUNOTHERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENT OF CASH FLOWS**  
**For the Nine Months Ended September 30, 2003 and 2002**  
**(Unaudited)**

	<u>September 30, 2003</u>	<u>September 30, 2002</u>
<b>Cash Flows from Operating Activities:</b>		
Net Loss	\$ (8,661,200)	\$ (10,354,100)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	1,293,800	1,227,300
Amortization of Deferred Compensation	46,000	□
Changes in Assets and Liabilities:		
Accounts Receivable	(337,600)	(1,857,100)
Inventories	□	71,500
Prepaid and Other Current Assets	(156,500)	(367,500)
Increase in Other Assets	□	(13,400)
Accounts Payable and Accrued Expenses	(279,600)	(1,246,700)
Deferred Revenue	(360,800)	(3,192,300)
Net Cash Used in Operating Activities	<u>(8,455,900)</u>	<u>(15,732,300)</u>
<b>Cash Flows from Investing Activities:</b>		
Acquisition of Property and Equipment	(167,800)	(392,000)
Increase in Patents	(142,800)	(225,700)
Cash Paid for Acquisition of Universal Preservation Technologies, Inc. Assets	(2,000,000)	□
Net Cash Used in Investing Activities	<u>(2,310,600)</u>	<u>(617,700)</u>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from Stock Issuance	9,274,600	□
Proceeds from Exercise of Stock Options and Warrants	10,900	41,200
Purchases of Treasury Stock	(91,300)	(43,100)
Net Cash (Used In) Provided by Financing Activities	<u>9,194,200</u>	<u>(1,900)</u>
Decrease in Cash and Cash Equivalents	(1,572,300)	(16,351,900)
Cash and Cash Equivalents at Beginning of Period	25,070,700	42,665,900
Cash and Cash Equivalents at End of Period	<u>\$ 23,498,400</u>	<u>\$ 26,314,000</u>

*See accompanying notes to unaudited consolidated financial statements*

**AVANT IMMUNOTHERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements**  
**September 30, 2003**

**(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 against viral and bacterial diseases, including single-dose oral vaccines aimed at protecting travelers and people in endemic regions from cholera, typhoid fever and other illnesses. In addition, the Company is conducting clinical studies of a proprietary vaccine candidate for cholesterol management. 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) Interim Financial Statements**

The accompanying unaudited consolidated financial statements for the three months and nine months ended September 30, 2003 and 2002 include the consolidated accounts of AVANT, and have been prepared in accordance with generally accepted accounting principles and with the 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 financial position at September 30, 2003, the results of operations for the three- and nine-month periods ended September 30, 2003 and 2002, and the cash flows for the nine-month periods ended September 30, 2003 and 2002. The results of operations for the three- and nine-month periods ended September 30, 2003 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, 2002, are adequate to make the information presented not misleading.

**(3) Recent Accounting Pronouncements**

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57, and 107 and rescission of FASB Interpretation No. 34* ("FIN 45"), which requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken by issuing the guarantee. The Interpretation also requires additional disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees it has issued. The accounting requirements for the initial recognition of guarantees are applicable on a prospective basis for guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for all guarantees outstanding, regardless of when they were issued. The adoption of FIN No. 45 did not have a material effect on our consolidated financial statements. The following is a summary of our agreement that we have determined is within the scope of FIN No. 45.

As permitted under Delaware law, our Third Restated Certificate of Incorporation, as amended, provides that AVANT will indemnify its officers and directors for certain claims asserted against them in

connection with their service as an officer or director of AVANT. The maximum potential amount of future payments that we could be required to make under these indemnification provisions is unlimited. However, we have never made any payments under these indemnification arrangements and we have purchased certain Directors' and Officers' insurance policies that reduce AVANT's monetary exposure and enable it to recover a portion of any future amounts paid. We believe the estimated net fair value of these indemnification arrangements is minimal.

In January 2003, the FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51* (FIN 46). The primary objective of the Interpretation is to provide guidance on the identification of, and financial reporting for, entities over which control is achieved through means other than voting rights; such entities are known as variable-interest entities (VIEs). Although the FASB's initial focus was on special-purpose entities (SPEs), the final guidance applies to a wide range of entities. FIN 46 applies immediately to entities created or obtained after January 31, 2003. FIN 46 applies to entities created before February 1, 2003 as of the beginning of the first interim period beginning after December 15, 2003. FIN 46 will be the guidance that determines (1) whether consolidation is required under the "controlling financial interest" model of Accounting Research Bulletin No. 51 (ARB 51), Consolidated Financial Statements, or (b) other existing authoritative guidance, or, alternatively, (2) whether the variable-interest model under FIN 46 should be used to account for existing and new entities. The Company believes that the adoption of FIN 46 will not have a material impact on our financial statements.

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" ("SFAS 150"). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 did not have a material effect on the Company's financial statements.

**(4) Property and Equipment**

Property and equipment includes the following:

	<u>September 30, 2003</u>	<u>December 31, 2002</u>
Laboratory Equipment	\$ 2,414,000	\$ 2,323,800
Office Furniture and Equipment	1,617,000	1,577,500
Leasehold Improvements	1,650,700	1,612,600
Property and Equipment, Total	5,681,700	5,513,900
Less Accumulated Depreciation and Amortization	(4,708,800)	(4,394,400)
	<u>\$ 972,900</u>	<u>\$ 1,119,500</u>

**(5) Intangible and Other Assets**

Intangible and other assets include the following:



	Estimated Lives	September 30, 2003	December 31, 2002
Capitalized Patent Costs	10 years	\$ 2,886,400	\$ 2,743,600
Accumulated Amortization		(1,801,400)	(1,568,300)
Capitalized Patent Costs, Net		1,085,000	1,175,300
<b>Acquired Intangible Assets:</b>			
Collaborative Relationships	5 years	1,090,000	1,090,000
Core Technology	10 years	3,786,900	1,786,900
Developed Technology	7 years	3,263,100	3,263,100
Strategic Partner Agreement	17 years	2,563,900	2,563,900
Accumulated Amortization		(3,492,800)	(2,746,500)
Acquired Intangible Assets, Net		7,211,100	5,957,400
Other Non Current Assets		84,700	84,700
		<u>\$ 8,380,800</u>	<u>\$ 7,217,400</u>

All of our intangible assets are amortized over their useful lives. Total amortization expense for intangible assets was \$248,800 and \$746,300 for the three-month and nine-month periods ended September 30, 2003 and \$198,800 and \$596,400 for the three-month and nine-month periods ended September 30, 2002.

The estimated future amortization expense of intangible assets as of September 30, 2003 for the remainder of fiscal year 2003 and the five succeeding years is as follows:

Year ending December 31,	Estimated Amortization Expense
2003 (remaining three months)	\$ 248,800
2004	995,100
2005	995,100
2006	995,100
2007	956,300
2008	956,300

**(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. We have 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, 2003 and 2002 as their inclusion would have been anti-dilutive. A total of 3,884,600 and 5,073,900 stock options and warrants were excluded from the computation of weighted average common shares as of September 30, 2003 and 2002, respectively, as they were anti-dilutive.

**(7) Stock Options**

We periodically grant 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. We account for such stock option grants using the intrinsic value method and intend to continue to do so.

The following are pro forma net loss and 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 months ended September 30,	
	2003	2002	2003	2002
<b>Net Loss:</b>				
As reported	\$ 2,115,700	\$ 276,200	\$ 8,661,200	\$ 10,354,100
Add: Stock-based compensation included in net loss applicable to common stockholders, as reported	46,000	□	46,000	□
Less: Total stock-based employee compensation expense determined under fair value based method for all awards	(256,600)	(177,800)	(688,900)	(723,100)
Pro forma	<u>2,326,300</u>	<u>454,000</u>	<u>9,304,100</u>	<u>11,077,200</u>
<b>Basic and Diluted Net Loss Per Share:</b>				
As reported	\$ 0.03	\$ 0.01	\$ 0.14	\$ 0.17
Pro forma	0.04	0.01	0.15	0.18

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 ended September 30,		Nine months ended September 30,	
	2003	2002	2003	2002
Expected stock price volatility	109%	109%	109%	109%
Expected option term	5 Years	2.5 Years	5 Years	2.5 Years
Risk-free interest rate	2.5 - 3.6%	1.0 - 3.8%	2.1 - 3.6%	1.0 - 4.6%
Expected dividend yield	None	None	None	None

Because the determination of the fair value of all options granted includes an expected volatility factor in addition to the factors detailed in the table above, and 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.

**(8) Share Repurchase Plan**

On August 16, 2002, the Company announced that its Board of Directors had authorized the repurchase of up to 2 million shares of the Company's common stock. The repurchased stock provides the Company with treasury shares for general corporate purposes, such as stock to be issued under employee stock option and stock purchase plans. The share repurchase plan expired as of August 31, 2003. The Company purchased 220,300 shares through September 30, 2003 at a cost of \$227,700.

**(9) Acquisition of Certain Assets of 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 based in San Diego, California, and the licensure of certain patent rights from Elan Drug Delivery Limited (a subsidiary of Elan Corporation plc). As part of the acquisition, Elan Drug Delivery Limited (EDD) settled a patent interference with UPT. Under the settlement agreement UPT assigned certain patent rights to EDD and

EDD licensed UPT's and other related patents to AVANT. EDD's license to AVANT gives AVANT exclusive rights in connection with those patents relating to orally administered vaccines and non-exclusive rights in certain other fields.

Through this transaction, AVANT has gained exclusive rights to UPT's VitriLife® process 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, thus eliminating the need for costly cold-chain distribution and storage of vaccines — the major challenge to vaccine affordability in many areas of the world facing endemic disease. The acquisition of UPT's assets includes only technology and patents; AVANT has not acquired UPT's San Diego facility or employees in this transaction. We have determined that the VitriLife® 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 the asset over their estimated lives of ten years.

**(10) Product Development and Licensing Agreements**

Our revenue from product development and licensing agreements was received pursuant to contracts with different organizations. Total revenue recognized by us in connection with these contracts for the three- and nine-month periods ended September 30, 2003 were approximately \$1,232,900 and \$1,620,000, respectively, and for the years ended December 31, 2002, 2001 and 2000 were approximately \$6,412,400, \$2,999,800 and \$729,800, respectively. A summary of these contracts follows:

*(A) Novartis Pharma AG*

In 1997, we entered into an option agreement with Novartis Pharma AG ("Novartis"), a worldwide pharmaceutical company headquartered in Basel, Switzerland, relating to the development of TP10 for use in xenotransplantation (animal organs into humans) and allotransplantation (human to human). Under the agreement, we received annual option fees and supplies of TP10 for clinical trials in return for granting Novartis a two-year option to license TP10 with exclusive worldwide (except Japan) marketing rights. In July 1999, Novartis exercised its option to license TP10 for use in the field of transplantation. Novartis made a \$2.3 million equity investment and a \$3.7 million license fee payment, which was received by AVANT in January 2000, as consideration for the license. AVANT has no obligation to incur any research and development costs in connection with this agreement. As of September 6, 2002, Novartis and AVANT agreed to terminate the TP10 agreement pursuant to which Novartis paid a net termination fee of \$1.9 million and returned to AVANT all pre-clinical and clinical TP10 material. The termination resulted in recognition of the remaining \$2,461,700 in deferred revenue related to the Novartis agreement.

*(B) GlaxoSmithKline plc*

During 1997, AVANT entered into an agreement with GlaxoSmithKline plc ("Glaxo") to collaborate on the development and commercialization of our oral rotavirus vaccine. Under the terms of the agreement, Glaxo received an exclusive worldwide license to commercialize AVANT's rotavirus vaccine. We were 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 and, in June 1999, we 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. 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 license fees of \$400,000 and \$300,000 in 2002 and 2001, respectively. In connection with the initiation by Glaxo of Phase III clinical trials of Rotarix® in the third quarter of 2003, AVANT recognized a \$1.0 million milestone. Glaxo has agreed to make further

payments, which could total up to \$7.5 million, upon the achievement of specified milestones. In addition, we will be entitled to royalties based on net sales of the rotavirus vaccine.

*(C) Aventis Pasteur*

In 1994, AVANT entered into a license agreement with Aventis Pasteur (“Aventis”) which granted Aventis the exclusive right to make, use and sell Adjumer® formulated vaccines for prevention of influenza, Lyme disease and diseases caused by meningococcus and the co-exclusive right (exclusive, except for the right of AVANT or one other person licensed by AVANT) to make, use and sell Adjumer® formulated vaccines directed against five other pathogens, including pneumococcus and RSV. AVANT has no obligation to incur any research and development costs in connection with this agreement. In connection with the formation of Parallel Solutions, Inc. (“Parallel”) in October 2001, AVANT assigned all of its rights and obligations under the Aventis license agreements to Parallel.

*(D) Pfizer Inc*

In connection with our acquisition of Megan, we 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 2002, we received a development milestone payment of \$500,000. Under the agreement, we may receive additional milestone payments of up to \$3 million based upon attainment of specified milestones. AVANT has no obligation to incur any research and development costs in connection with this agreement. We have 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.

*(E) DynPort Vaccine Company LLC*

In October 2001, AVANT granted DynPort Vaccine Company LLC (DVC) a license for exclusive rights to use certain components of AVANT’s vaccine technology. Financial terms of the agreement with DVC include annual license fees, milestone payments of up to \$700,000 and royalty payments on eventual product sales. 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. We have received since October 2001, \$200,000 in payments for the delivery of materials and \$100,000 in milestone payments from DVC. AVANT has no obligation to incur any research and development costs in connection with this license.

**(11) Subcontracts with DynPort Vaccine Company LLC**

In January 2003, AVANT was awarded a subcontract to develop for the U.S. Department of Defense an oral combination vaccine against anthrax and plague using AVANT’s proprietary vaccine technologies. AVANT executed this initial subcontract with DynPort Vaccine Company LLC (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 two additional subcontracts marking further milestones in the company’s efforts with DVC to develop anthrax and plague vaccines for the U.S. Department of Defense. The first award, in the amount of \$344,000, covers stability testing of DVC’s injectable anthrax vaccine, which began Phase I clinical testing in October 2002. The second award, for approximately \$1.3 million, supports preclinical animal testing of vaccine constructs being developed by AVANT for the oral combination vaccine against anthrax and plague. AVANT expects to execute additional subcontracts with DVC. Including the awards above, AVANT may receive under the agreements in excess of \$8 million over a two-year period through 2004, covering vaccine development through preclinical testing.

**(12) Acquisition of Pharmacia Intellectual Property**

In March 2003, AVANT acquired intellectual property, including a portfolio of pending patent applications, from Pharmacia Corporation for \$200,000 in cash and contingently issuable warrants to acquire up to 300,000 shares of AVANT common stock in three tranches of 100,000 warrants each. The warrants are to be issued upon achievement by AVANT of defined future milestones and will have an exercise price equal to the fair market value of AVANT's common stock on the day granted. If AVANT were to issue these warrants, AVANT would record an expense equal to the fair market value of the warrants on the date of grant. The patent applications are directed to products or methods for stimulating an immune response against cholesteryl ester transfer protein (CETP), which mediates an important cholesterol transport mechanism. The payment of \$200,000 was recorded as a research and development expense during the first quarter of 2003.

**(13) Private Stock Offering**

In July 2003, AVANT completed a private placement of approximately 4,444,444 shares of common stock and warrants to purchase 444,444 shares of common stock at \$3.00 per share to an institutional investor. Gross proceeds from the offering totaled \$10 million. Expenses associated with the transaction were approximately \$775,000.

**(14) Deferred Compensation**

During the quarter, AVANT awarded 400,000 restricted shares to an officer of the company that are subject to vesting. The fair market value of the stock at the date of grant was \$1,104,000 and has been recorded as deferred stock-based compensation. Deferred stock-based compensation is amortized straight-line over the vesting term of the restricted stock awards and recognized as compensation expense.

**Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995:** *This quarterly report on Form 10-Q 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 plague or any other microbes used as bioweapons and other disease causing agents; (3) the ability to successfully complete development and commercialization of TP10, CholeraGarde™(Peru-15), Ty800, CETi-1 and of other products; (4) the cost, timing, scope and results of ongoing safety and efficacy trials of TP10, CholeraGarde™(Peru-15), Ty800, CETi-1 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, CholeraGarde™(Peru-15), Ty800, CETi-1 and other products; (6) the ability of the Company to manage multiple late stage clinical trials for a variety of product candidates; (7) changes in existing and potential relationships with corporate collaborators; (8) the cost, delivery and quality of clinical and commercial grade materials supplied by contract manufacturers; (9) the timing, cost and uncertainty of obtaining regulatory approvals to use TP10, for among other purposes, for adults undergoing cardiac surgery, to use CholeraGarde™(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; (10) the ability to obtain substantial additional funding; (11) the ability to develop and commercialize products before competitors; (12) the ability to retain certain members of management; and (13) 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 forward-looking 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 principle activity since our inception has been research and product development conducted on our own behalf, as well as through joint development programs with several pharmaceutical companies and other collaborators. We were incorporated in the State of Delaware in December 1983.

### **CRITICAL ACCOUNTING POLICIES**

Our 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 2002 Form 10-K. There have been no changes to these policies since December 31, 2002. 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. We have assembled a broad portfolio of technologies and intellectual property that give us a strong competitive position in the vaccines arena and five of our vaccines are in clinical development. 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. Our goal is to become a leading developer of such innovative vaccines that address health care needs on a global basis.

We have actively developed and acquired innovative technologies – especially novel approaches to vaccine creation. Today our broad intellectual property position allows us to respond quickly and leverage our expertise into many different areas as opportunities and needs arise. For example, our vaccine technology for providing rapid protection against bacterial illnesses 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. Our 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 us to maximize the overall value of our technology and product portfolios 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 based in San Diego, California, and the licensure of certain patent rights from Elan Drug Delivery Limited (a subsidiary of Elan Corporation plc). As part of the acquisition, Elan Drug Delivery Limited (EDD) settled a patent interference with UPT. Under the settlement agreement UPT assigned certain patent rights to EDD, and EDD licensed UPT’s and other related patents to AVANT. EDD’s license to AVANT gives AVANT exclusive rights in connection with those patents relating to orally administered vaccines, and non-exclusive rights in certain other fields.

Through this transaction, AVANT has gained exclusive rights to UPT’s VitriLife® process 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, thus eliminating the need for costly cold-chain distribution and storage of vaccines – the major challenge to vaccine affordability in many areas of the world facing endemic disease. The acquisition of UPT’s assets includes only technology and patents; AVANT did not acquire UPT’s San Diego facility or employees in this transaction. We have determined that the VitriLife® 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, we recorded a charge of \$9,012,300 for acquired in-process research and development (“IPR&D”), which represented purchased technology which had not yet reached technological feasibility and had no alternative future use. The value of IPR&D was determined by estimating the costs to develop the purchased in-process technology into commercially viable products, estimating the net cash flows from such projects and discounting the net cash flows back to their present values. The probability of success and discount rates in each project take into account the uncertainty surrounding the successful development and commercialization of the purchased in-process technology. The resulting net cash flows for these projects were based on our best estimates of revenue, cost of sales, research and development costs, selling, general and administrative costs, and income taxes for each project, and the net cash flows reflect assumptions that would be used by market participants.

*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, we 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, 2003, none of the acquired research and development projects had reached technical feasibility.

## RESEARCH AND DEVELOPMENT ACTIVITIES

AVANT is currently focused on the development of a number of vaccine product candidates which are in various stages of clinical trials. We expect that a large percentage of our research and development expenses will be incurred in support of our 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 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:

Clinical Phase	Estimated Completion Period
Phase I	1-2 Years
Phase II	1-5 Years
Phase III	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 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.

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 2000, is set forth below under "Program Developments." During the past five years through the end of 2002, AVANT incurred an aggregate of \$60.6 million in research and development costs. During the nine months ended September 30, 2003, AVANT incurred an aggregate of \$7.9 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 years ended December 31, 2002, 2001 and 2000 and the nine months ended September 30, 2003 and 2002. 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.

	Nine Months Ended September 30,		Year Ended December 31,		
	2003	2002	2002	2001	2000
<i>Cholesterol Management Vaccine:</i>					
CETi-1	\$ 2,771,200	\$ 2,322,600	\$ 3,176,800	\$ 2,387,700	\$ 1,900,100
<i>Bacterial Vaccines:</i>					
CholeraGarde	929,200	5,070,600	5,959,100	2,369,200	134,200
Ty800	303,100	1,834,600	2,203,600	1,863,500	66,100
Other	780,300	—	204,400	—	—
<i>BioDefense Vaccines:</i>	1,904,400	6,100	239,900	—	—
<i>Food Safety &amp; Animal Health Vaccines:</i>	46,300	432,300	450,600	984,900	64,800
<i>Viral Vaccines:</i>					
Rotavirus vaccine	375,000	300,000	400,000	334,100	244,900
Other	54,300	306,800	346,800	264,600	1,366,500
<i>Complement Inhibitors:</i>					
TP10/TP20	712,200	1,617,300	1,714,800	12,930,500	6,514,600
<i>Discontinued Programs:</i>	—	8,900	12,500	446,000	483,000
<i>Total R&amp;D Expense</i>	<u>\$ 7,876,000</u>	<u>\$ 11,899,200</u>	<u>\$ 14,708,500</u>	<u>\$ 21,580,500</u>	<u>\$ 10,774,200</u>

## PROGRAM DEVELOPMENTS

*Cholesterol Management Vaccine:* We are 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). We are developing this vaccine, CETi-1, to stimulate an immune response against CETP, which we believe may improve the ratio of HDL to LDL cholesterol and reduce the progression of atherosclerosis. We have conducted preliminary studies of rabbits, which have demonstrated the ability of CETi-1 vaccine to elevate HDL and reduce the development of blood vessel lesions.

CETi-1 is being developed for the management of patients with low levels of HDL cholesterol. In September 1999, we 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 (allergic reaction to shower gel) 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 study medication, suggesting a dose-response relationship.

The CETi-1 program moved 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. On October 22, 2003, AVANT announced positive preliminary results from this clinical study. Results showed that the CETi-1 vaccine was well-tolerated, immunogenic and produced an increase in HDL-cholesterol from baseline in all groups. For the high dose group, the increase in HDL-cholesterol from baseline was statistically significant. This increase was greater than the increase in HDL-cholesterol for the placebo population, but the difference was not statistically significant. We looked at two groups of patients in this study – one group, approximately two thirds of the patients, were currently not taking statin therapy while the other, representing one third of the patients, were on statin therapy. In the first group – the patients not currently taking statins, the high dose group of patients again showed an 8.4% increase in HDL cholesterol. This result was clearly statistically significant from both baseline and placebo. However, for the population using statins, the study did not show significant changes in HDL cholesterol. Finally, the results showed that in a very high percentage of the patients treated, approximately 90%, the vaccine elicited anti-CETP antibodies. This fact, combined with the overall increase in HDL levels, we believe validates the scientific rationale behind this vaccine – that antibodies against CETP can produce an effect on HDL cholesterol levels in humans.

During the period January 1, 2000 through December 31, 2002, AVANT incurred approximately \$7.5 million in research, development and clinical costs. During the nine months ended September 30, 2003, AVANT incurred approximately \$2.8 million in research, development and clinical costs associated with the CETi-1 program. As clinical data become available, we plan to seek a corporate partner to complete development and to commercialize the CETi-1 vaccine.

*Bacterial Vaccines:* 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 before moving into progressively younger pediatric populations, eventually studying the vaccine in infants as young as nine months. To date, IVI has completed testing in adults and is now vaccinating

toddlers, ages 2 to 5 years. AVANT expects IVI to provide data from the adult portion of this study during the fourth quarter of 2003.

During the second quarter of 2003, AVANT terminated its manufacturing contract with Bio Sidus, S.A., of Buenos Aires, Argentina, for the manufacture of its CholeraGarde™ vaccine. Simultaneously, AVANT has commenced arbitration proceedings in the State of New York to reconcile contractual issues between the two companies. AVANT believes it has fully accrued for any potential costs. Clinical material for the IVI trials in Bangladesh previously has been manufactured by the Walter Reed Army Institute of Research (WRAIR), and AVANT and WRAIR have entered into a manufacturing agreement to supply CholeraGarde™.

During the period January 1, 2000 through December 31, 2002, AVANT incurred approximately \$8.5 million in research, development and clinical costs on its CholeraGarde™ program. During the nine months ended September 30, 2003, AVANT incurred approximately \$0.9 million in research, development and clinical costs on its CholeraGarde™ program.

In addition, 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 typhoid fever 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, 2002, AVANT incurred approximately \$4.1 million in research, development and clinical costs on its Ty800 program. During the nine months ended September 30, 2003, AVANT incurred approximately \$0.3 million in research, development and clinical costs on its Ty800 program.

Finally, we are 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.

We have recently completed the acquisition of VitriLife®, a new technology with the potential to reduce manufacturing costs and improve product stability, eliminating the need for vaccine refrigeration. With this technology and our *Cholera* - and *Salmonella*-vectored delivery technologies, named VibrioVec™ and SalmoVec™, we 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.

*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. We believe our 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 technology and advanced production processes licensed from AVANT. DVC hopes this vaccine will offer a safe, effective product to support the country's need for a new-generation anthrax vaccine. The Phase I trial is being conducted at WRAIR in conjunction with the Henry M. Jackson Foundation. The study will evaluate tolerability, safety and immunogenicity of DVC's new vaccine being developed for the U.S. Department of Defense (DoD) through the Joint Vaccine Acquisition Program (JVAP). 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 the project being fully funded through completion and AVANT performing and continuing to demonstrate that it has the capability to perform the funded work.

In July 2002, AVANT was awarded a Phase I Small Business Innovation Research (SBIR) grant to support the development of the Company's oral, single-dose bacterial vectors to immunize people against anthrax. Vaccine delivery using live, attenuated bacteria is particularly well suited for situations where ease of administration and rapid onset of immunity are required, such as for protection against biological warfare agents. The NIAID of the NIH awarded this Live Attenuated Vaccines Against Anthrax grant, which provides approximately \$125,000 in funding to AVANT.

Further, in January 2003, AVANT was awarded a subcontract to develop for the U.S. Department of Defense 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. AVANT expects to execute additional subcontracts with DVC. Under the subcontract agreement, AVANT may receive in excess of \$8 million over a two-year period through 2004, covering vaccine development through preclinical testing. Towards the \$8 million goal, AVANT has been awarded subcontracts totaling approximately \$4.1 million in 2003 and the Defense Appropriations Bill for Fiscal Year 2004 passed by Congress in September 2003 commits an additional \$3.0 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.

In August 2003, the Company announced that it had reached agreement with MassDevelopment, the economic development entity for the Commonwealth of Massachusetts, for AVANT to occupy and build-out a process development and pilot-manufacturing facility in Fall River, Massachusetts. It is expected that MassDevelopment will provide financing for AVANT to establish this 11,600 square foot facility, which will support the clinical development of its portfolio of bacterial vaccines, including vaccines for biodefense, as well as the continued development and product application of VitriLife®.

During the period January 1, 2000 through December 31, 2002, AVANT incurred approximately \$0.2 million in research and development costs on its biodefense vaccine program. During the nine months ended September 30, 2003, AVANT incurred approximately \$1.9 million in research and development costs on its biodefense vaccine program.

*Food Safety and Animal Health Vaccines:* AVANT has also partnered with Pfizer, who will apply AVANT's vaccine technologies to animal health and human food safety markets. The Pfizer research programs are making significant progress and in late 2002 we achieved an important milestone, which resulted in a modest payment to AVANT. During the period January 1, 2000 through December 31, 2002, 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, 2003, AVANT incurred approximately \$46,300 in research and development costs on its food safety and animal health vaccines program.

*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, we licensed our oral rotavirus vaccine to Glaxo. In 1999, after our Phase II study demonstrated 89% protection in a study involving 215 infants, Glaxo paid us 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, 2002, AVANT incurred approximately \$900,000 in licensing fees and \$79,000 in research and development costs. During the nine months ended September 30, 2003, AVANT incurred approximately \$375,000 in licensing fees associated

with the rotavirus 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. Glaxo has completed Phase I/II bridging studies in over 6,000 infants in Europe, Latin America and 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. Assuming product development and commercialization continues satisfactorily, we may receive additional milestone payments totaling \$7.5 million upon the achievement of specified milestones. In addition, we will be entitled to royalties based on net sales of Rotarix®.

*Complement Inhibitors:* In 1997, we entered into an agreement with Novartis relating to the development of our complement inhibitor, TP10, for use in xenotransplantation (animal organs into humans) and allotransplantation (human organs into humans). The decision to license TP10 resulted in a \$6 million equity investment and license payment by Novartis which was received by AVANT in January 2000. As of September 6, 2002, Novartis and AVANT agreed to terminate the TP10 agreement pursuant to which Novartis paid a net termination fee of \$1.9 million and returned to AVANT all pre-clinical and clinical TP10 material.

In February 2002, AVANT announced that TP10 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. Adverse events reported following treatment with TP10 were generally similar to those seen in placebo treated patients and were said by investigators to be routinely observed following cardiopulmonary bypass.

The important treatment benefits seen in the male population were directly related to mortality and the benefit seen was impressive. This further analysis of the study data showed continued promise for this molecule and AVANT has announced its renewed commitment to its development. AVANT plans to conduct a Phase II double-blind, placebo-controlled trial of TP10 in approximately 200 women undergoing cardiopulmonary by-pass surgery. The trial will examine the effect of TP10 versus placebo, is planned to begin around year-end 2003 and conclude around year-end 2004, and will be conducted at approximately 10 sites throughout the United States. The goals of the trial are to clarify the effect that TP10 has for women undergoing cardiac surgery, as well as augment the safety data for that patient population to allow for the design of a subsequent registration-directed trial.

During the period January 1, 2000 through December 31, 2002, AVANT incurred approximately \$21.2 million in research, development and clinical costs. During the nine months ended September 30, 2003, AVANT incurred approximately \$0.7 million in research, development and clinical costs associated with its complement programs. With the termination of the Novartis agreement, AVANT can now offer a worldwide license for all fields, and may seek partnering arrangements to capture the value inherent in this program and its strong intellectual property portfolio.

## **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. DVC, a private 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 diseases and contagious diseases, initiated under the 1997 Joint Vaccine Acquisition Program.

## RESULTS OF OPERATIONS

### Three-Month Period Ended September 30, 2003 as Compared With the Three-Month Period Ended September 30, 2002

AVANT reported consolidated net loss of \$2,115,700, or \$.03 per share, for the third quarter ended September 30, 2003, compared with a net loss of \$276,200, or \$.01 per share, for the third quarter ended September 30, 2002. The weighted average common shares outstanding used to calculate net loss per common share was 64,703,000 in 2003 and 60,457,800 in 2002.

*Revenue:* Total revenue decreased \$2,545,300, or 55.8%, to \$2,015,100 for the third quarter of 2003 compared to \$4,560,400 for the third quarter of 2002.

Product development and licensing revenue decreased \$3,261,000, or 72.6%, to \$1,232,900 in 2003 from \$4,493,900 in 2002. In 2003, the decrease in product development and licensing revenue consisted primarily of a decrease of \$2,153,900 for the amortization of a nonrefundable license fee in 2002 and the recognition of a \$1.9 million net termination fee from Novartis due to the termination of the TP10 agreement with Novartis in the third quarter of 2002, offset in part by the recognition of a \$1 million milestone payment from Glaxo in the third quarter of 2003. The decrease in product development and licensing revenue in 2003 further consists of a decrease of \$106,600 for the amortization of nonrefundable license fees from Pfizer due to a revised estimate of the amortization period and a decrease of \$125,000 in funded research from Pfizer, offset partly by an increase of \$24,300 received in connection with government SBIR grants.

During the first nine months of 2003, AVANT received three 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 in the aggregate amount of \$4.1 million. Under these agreements, AVANT recognized \$733,700 in government contract revenue during the third quarter of 2003.

As of September 1, 2002, we transferred the marketing and distribution of the Megan poultry product line to our partner, Lohmann Animal Health International (LAHI), and in the third quarter of 2003 AVANT received a percentage of all Megan®Vac 1 product sales as product royalty payments totaling \$48,500. Product sales for the third quarter of 2002 totaled \$66,500 and were derived from direct sales by AVANT of the Megan®Vac 1 salmonella vaccine product.

*Operating Expense:* Total operating expense decreased \$775,300, or 15.6%, to \$4,182,600 for the third quarter of 2003 compared to \$4,957,900 for the third quarter of 2002. The decrease in total operating expense for the third quarter of 2003 compared to 2002 is primarily due to a reduction in costs associated with conducting clinical trials, a decrease in contract manufacturing activities and consulting costs associated with the bacterial vaccines programs, and a decrease in personnel and related expenses.

Research and development expense decreased \$913,100, or 26.7%, to \$2,510,100 in 2003 from \$3,423,200 for the third quarter of 2002. The decrease in 2003 compared to 2002 is primarily due to reductions in contract manufacturing costs of \$42,000, consulting costs of \$105,500 and clinical trial costs of \$574,600 associated with the company's bacterial vaccine programs. It also reflects declines in personnel and related expenses of \$219,600, and facility related expenses of \$30,900.

Selling, general and administrative expense increased \$98,100, or 7.4%, to \$1,423,700 in 2003 compared to \$1,325,600 for the third quarter of 2002. The increase in expense in 2003 compared to 2002 is primarily attributed to an increase in legal expenses of \$192,600 and insurance expenses of \$38,200, offset partly by a decrease in consulting expenses of \$99,000.

Amortization expense of acquired intangible assets was \$248,800 in 2003 compared to \$198,800 in 2002.

*Investment Income, Net:* Interest income decreased \$69,500, or 57.3%, to \$51,800 for the third quarter of 2003 compared to \$121,300 for the third quarter of 2002. The decrease is primarily due to lower average cash balances and lower interest rates during the third quarter of 2003 compared to the third quarter of 2002. During the third quarters of 2003 and 2002, the average month-end cash balances were \$24,561,200 and \$27,763,900, respectively. The effective interest rates during the third quarters of 2003 and 2002 were 0.98% and 1.79%, respectively.

Nine-Month Period Ended September 30, 2003 as Compared  
with the Nine-Month Period Ended September 30, 2002

AVANT reported consolidated net loss of \$8,661,200, or \$.14 per share, for the nine months ended September 30, 2003, compared with a net loss of \$10,354,100, or \$.17 per share, for the nine months ended September 30, 2002. The weighted average common shares outstanding used to calculate net loss per common share was 61,773,500 in 2003 and 60,458,500 in 2002.

*Revenue:* Total revenue decreased \$2,118,800, or 35.9%, to \$3,775,200 for the first nine months of 2003 compared to \$5,894,000 for the first nine months of 2002.

Product development and licensing revenue decreased \$3,981,600, or 71.1%, to \$1,620,000 for the first nine months of 2003 from \$5,601,600 for the first nine months of 2002. In 2003, the decrease in product development and licensing revenue consisted primarily of a decrease of \$2,461,700 for the amortization of a nonrefundable license fee and the recognition of a \$1.9 million net termination fee from Novartis due to the termination of the TP10 agreement with Novartis in 2002, offset in part by the recognition of a \$1 million milestone payment from Glaxo in 2003. The decrease in product development and licensing revenue in 2003 further consists of a decrease of \$319,700 for the amortization of nonrefundable license fees from Pfizer due to an extension of the amortization period, a decrease of \$365,000 in funded research from Pfizer, a decrease of \$25,000 in milestone payments from DynPort received in 2002, offset partly by a one-time \$50,000 distribution fee from LAHI, and \$39,600 received in connection with government SBIR grants.

During the first nine months of 2003, AVANT received three 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 in the aggregate amount of \$4.1 million. Under these agreements, AVANT recognized \$2,029,300 in government contract revenue during the first nine months of 2003.

As of September 1, 2002, we transferred the marketing and distribution of the Megan poultry product line to our partner, LAHI, and for the first six months of 2003 AVANT received a percentage of all Megan®Vac 1 product sales as product royalty payments totaling \$125,900. Product sales for the first nine months of 2002 totaled \$292,400 and were derived from sales of our Megan®Vac 1 salmonella vaccine product.

*Operating Expense:* Total operating expense decreased \$4,113,100, or 24.6%, to \$12,622,500 for the first nine months of 2003 compared to \$16,735,600 for the first nine months of 2002. The decrease in total operating expense for the first nine months of 2003 compared to the first nine months of 2002 is primarily due to a reduction in costs associated with conducting sponsored research and clinical trials, a decrease in contract manufacturing activities and consulting costs associated with the bacterial vaccines programs, and a decrease in personnel and related expenses. During the second quarter of 2003, AVANT terminated its manufacturing contract with Bio Sidus, S.A., of Buenos Aires, Argentina, for the manufacture of its CholeraGarde™ vaccine. Simultaneously, AVANT has commenced arbitration proceedings in the State of New York to reconcile contractual issues between the two companies.

Research and development expense decreased \$4,023,200, or 33.8%, to \$7,876,000 for the first nine months of 2003 compared to \$11,899,200 for the first nine months of 2002. The decrease in 2003



compared to 2002 is primarily due to reductions in contract manufacturing costs of \$2,097,800, sponsored research costs of \$84,000 and clinical trial costs of \$1,496,100 associated with the company's bacterial vaccine programs. It also reflects declines in personnel and related expenses of \$399,400, and manufacturing consultancy costs of \$332,500, offset partly by increases in license fees of \$280,400.

Selling, general and administrative expense decreased \$198,900, or 4.7%, to \$4,000,100 for the first nine months of 2003 compared to \$4,199,000 for the first nine months of 2002. The decrease in 2003 is primarily attributed to decreases in selling and marketing expense of \$94,500, consulting costs of \$593,200 and in personnel and related expenses of \$37,700, offset partly by increases in legal expenses of \$466,200 and insurance expenses of \$125,600.

Amortization expense of acquired intangible assets was \$746,400 in the first nine months of 2003 compared to \$596,400 in 2002.

*Investment Income, Net:* Net investment income decreased \$231,900, or 63.3%, to \$186,100 for the first nine months of 2003 compared to \$487,500 for the first nine months of 2002. The decrease is primarily due to lower average cash balances and significantly lower interest rates during the first nine months of 2003 compared to the first nine months of 2002. During the first nine months of 2003 and 2002, the average month-end cash balances were \$21,088,800 and \$33,308,200, respectively. The effective interest rates during the first nine months of 2003 and 2002 were 1.16% and 1.87%, respectively.

## LIQUIDITY AND CAPITAL RESOURCES

AVANT ended the third quarter of 2003 with cash and cash equivalents of \$23,498,400 compared to cash and cash equivalents of \$25,070,700 at December 31, 2002.

Net cash used in operating activities decreased to \$8,455,900 for the first nine months of 2003 compared to \$15,732,300 for the first nine months of 2002. The decrease is primarily attributed to the decrease in net loss incurred in 2003 compared to 2002, smaller increases in accounts receivable of \$337,600 in 2003 compared to \$1,857,100 in 2002 and smaller decreases in deferred revenue of \$360,800 in 2003 compared to \$3,192,300 in 2002. The change in deferred revenue in 2002 was due to the recognition of deferred revenue as the result of the termination of the TP10 agreement with Novartis in the third quarter of 2002 and the change in accounts receivable in 2002 was because of a receivable of a \$1.9 million termination payment due from Novartis.

Net cash used in investing activities increased to \$2,310,600 for the first nine months of 2003 compared to \$617,700 for the first nine months of 2002. The increase is primarily due to \$2 million of cash paid for certain assets of Universal Preservation Technologies, Inc.

Net cash provided by financing activities was \$9,194,200 for the first nine months of 2003 compared to net cash used in financing activities of \$1,900 for the first nine months of 2002. The increase is due primarily to the completion of a private placement, offset by a decrease in proceeds from the exercise of stock options and warrants, and an increase in purchases of treasury stock under a share repurchase plan.

As of June 30, 2003, AVANT had future payments required under contractual obligations and other commitments approximately as follows:

	Total	Less than One Year	1-3 Years	4-5 Years
Operating lease obligations	\$ 7,790,600	\$ 581,300	\$ 6,499,600	\$ 709,700
Licensing obligations	614,000	149,000	275,000	190,000
Total future obligations	<u>\$ 8,404,600</u>	<u>\$ 730,300</u>	<u>\$ 6,774,600</u>	<u>\$ 899,700</u>

In July 2003, AVANT completed a private placement of approximately 4,444,444 shares and warrants to purchase 444,444 shares of common stock at \$3.00 per share to an institutional investor. Gross proceeds from the offering totaled \$10 million. Expenses associated with the transaction are expected to total approximately \$725,000.

AVANT believes that cash inflows from existing collaborations, interest income on invested funds and our current cash and cash equivalents will be sufficient to meet estimated working capital requirements and fund operations beyond December 31, 2004. 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 2003, we expect to 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, 2003 and December 31, 2002 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, within the 90 days prior to the date of this report, 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.

#### *Changes in Internal Control Over Financial Reporting.*

There was no 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.

## PART II — OTHER INFORMATION

### Item 6. Exhibits and Reports on Form 8-K

#### (a) Exhibits

- 10.1 Subcontractor Service Agreement by and between DynPort Vaccine Company LLC and AVANT, dated January 15, 2003.
- 10.2 Subcontract modification by and between DynPort Vaccine Company LLC and AVANT, dated May 27, 2003.
- 10.3 Subcontract by and between DynPort Vaccine Company LLC and AVANT, dated May 27, 2003.
- 10.4 Second Amendment to Amended and Restated Employment Agreement between AVANT and Una S. Ryan, Ph. D., dated as of September 18, 2003.
- 10.5 Restricted Stock Unit Agreement between AVANT and Una S. Ryan, dated September 18, 2003.
- 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

#### (b) Reports on Form 8-K

A Form 8-K was filed on July 2, 2003, regarding a press release announcing that AVANT had entered into a securities purchase agreement with an institutional investor in a private placement of unregistered securities of the Company.

A Form 8-K (Item 12) was filed on July 23, 2003 regarding a press release announcing that AVANT had reported its financial results for the second quarter ended June 30, 2003.

**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 6, 2003

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

Dated: November 6, 2003

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

## EXHIBIT INDEX

Exhibit No.	Description
10.1	Subcontractor Service Agreement by and between DynPort Vaccine Company LLC and AVANT, dated January 15, 2003.
10.2	Subcontract modification by and between DynPort Vaccine Company LLC and AVANT, dated May 27, 2003.
10.3	Subcontract by and between DynPort Vaccine Company LLC and AVANT, dated May 27, 2003.
10.4	Second Amendment to Amended and Restated Employment Agreement between AVANT and Una S. Ryan, Ph. D., dated as of September 18, 2003.
10.5	Restricted Stock Unit Agreement between AVANT and Una S. Ryan, dated September 18, 2003.
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

**SUBCONTRACTOR SERVICE AGREEMENT NO. DPSC02-02257**

This is a Time and Materials (T&M) SUBCONTRACTOR SERVICE AGREEMENT (hereinafter referred to as "Agreement") by and between DynPort Vaccine Company LLC (hereinafter referred to as "DVC"), a Virginia corporation, and AVANT Immunotherapeutics, Inc. (hereinafter referred to as "Subcontractor"), hereinafter referred to jointly as "the Parties".

Whereas, Subcontractor is, by reason of knowledge, education, and/or experience, capable of performing and desires to perform services for DVC in support of the U.S. Department of Defense Joint Vaccine Acquisition Program (JVAP) under U.S. Government Contract No. DAMD17-98-C-8024.

In consideration of the promises, mutual covenants, and agreements contained herein, the parties agree as follows:

**1. General Terms and Conditions**

The general conditions set forth in Attachment A, General Terms and Conditions, are incorporated herein.

**2. Scope of Work**

Subject to the terms and conditions of this Agreement, the Subcontractor will furnish the services described in Attachment B, Statement of Work.

**3. Term**

This Agreement shall be effective for the period December 31, 2002 through December 31, 2003, in accordance with Attachment C, Performance Schedule. DVC may immediately terminate in the event of the Subcontractor's breach of this Agreement, or if DVC's prime contractual support for the Subcontractor is terminated. DVC reserves the right to extend the term of this Agreement upon written notification to, and mutual agreement of, the Subcontractor.

**4. Authorized Funding**

- a. This Agreement has an authorized funded value of \$2,726,076.72, in accordance with Attachment D, Price Schedule. This value represents the maximum amount the Subcontractor is currently authorized to expend in performance of the work authorized hereunder.
- b. Subcontractor shall notify DVC's Subcontract Administrator, in writing, if Subcontractor believes that the costs which will become due to Subcontractor in the next sixty (60) days, when added to all other costs previously accrued, will exceed seventy-five percent (75%) of the authorized funding. That notice shall include an estimate of additional funds required. Subcontractor is not obligated to perform any work, and DVC is not obligated to reimburse Subcontractor for any work performed, if in performing that work Subcontractor exceeds the authorized funding.
- c. DVC reserves the right to change the authorized funded value of this Agreement if:
  - The Defense Contract Audit Agency (DCAA), following review of the Subcontractor indirect rates (Fringe, Overhead, and G&A) authorized hereunder, determines that those rates are unacceptable and must be modified.
  - Such change is deemed necessary by DVC to ensure the fairness and reasonableness of the authorized funded value of this Agreement.
- d. As required, the authorized funded value of this Agreement will be changed by issuance of bilateral modification(s) to this Agreement. The authorized funded value of this Agreement shall not exceed the maximum agreement value (ceiling value).

**5. Maximum Agreement Value (Ceiling Value)**

The maximum value of this Agreement (ceiling value) shall not exceed \$2,726,076.72. If Subcontractor, at any time during the performance of the work authorized hereunder, has reason to believe that the ceiling value specified herein will be insufficient to complete the work, Subcontractor shall notify DVC immediately, advising the reason(s) for such cost increase and providing a revised cost estimate with supporting cost justification. The ceiling value indicated herein shall not be exceeded without DVC's prior written approval.

---

**6. Options**

- a. DVC may, at its sole discretion, authorize Subcontractor to perform the following optional tasks, as presented in Subcontractor's original quotation, dated August 22, 2002, submitted in response to DVC Request for Quotation (RFQ) No. RQ02257:
  - Task 3.2 – Develop Production Processes for Live Bacterial Vector Vaccines
  - Task 3.3 – Develop Formulations and Preservation Methods for Live Bacterial Vector Vaccines
  - Task 3.5 – Demonstrate the Efficacy of Live Bacterial Vector Vaccines
- b. DVC reserves the right to require Subcontractor to submit updated quotations for the tasks presented in Paragraph 6a above prior to their award to Subcontractor.
- c. The options presented in Paragraph 6a above will be exercised solely at the discretion of DVC.
- d. The authorized funded and ceiling values of this Agreement will be modified as required to incorporate the addition of optional tasks.
- e. As required, the authorized funded and ceiling values of this Agreement will be changed by issuance of bilateral modification(s) to this Agreement. The authorized funded value of this Agreement shall not exceed the maximum agreement value (ceiling value).

**7. Direction**

The Subcontractor shall be responsible for its performance. The DVC Senior Scientist, Dr. Barbara Solow, shall provide **technical** direction and clarification regarding the scope of work. The DVC Subcontract Administrator, Roy Conley, is solely responsible for changes/modifications to the scope, schedule, and budget of this Agreement. No employment relationship between DVC and Subcontractor or its employees, Subcontractors, or agents shall be created by this Agreement.

**8. Consideration and Payment**

- a. As consideration for services to be provided here under, DVC will compensate Subcontractor per Attachment D, Price Schedule.
- b. All invoices shall be signed and dated by the Subcontractor and must reference this Agreement number and the following Contract Work Breakdown Structure (CWBS) numbers as appropriate, depending upon the task performed:
  - CWBS No. C.5.9.2.1: Construct Live Bacterial Vectors Using Genetically Engineered Strains of *V. cholerae*, *S. typhi*, or *S. typhimurium*
  - CWBS No. C.5.9.2.2: Clone Heterologous Antigens PA, F1, and V Into hlyA, inp, and/or Chromosomal Insertion Plasmids
  - CWBS No. C.5.9.2.3: Construct Live Bacterial Vector Strains Expressing Single Heterologous Antigens and/or Combinations of Antigens
  - CWBS No. C.5.9.2.4: Develop Methods to Quantify the Expression of PA and/or F1 and V Localized in Cytoplasmic and Extra-Cytoplasmic Compartments of Live Bacterial Vectors
  - CWBS No. C.5.9.2.5: Determine the Expression Level of PA, F1, and V in Live Bacterial Vector Strains
  - CWBS No. C.5.9.2.6: Develop Methods to Analyze the Biophysical Characteristics of PA and/or F1 and V, and Analyze the Integrity and Cellular Localization of the Respective Antigens
  - CWBS No. C.5.9.2.7: Construct Research Cell Banks of the Live Bacterial Vector Strains and Characterize the Cell Banks Using Appropriate Test Methods
  - CWBS No. C.5.9.2.8: Project Management
- c. Invoices shall be due and payable within thirty (30) days after receipt of an acceptable invoice and certification of the labor hours worked and purchases made. Invoices shall be submitted, in duplicate, to:

DynPort Vaccine Company LLC  
Attn.: Accounts Payable  
64 Thomas Johnson Drive  
Frederick, MD 21702  
Telephone: (301) 607-5000  
Fax: (301) 607-5068

Such invoice shall, at a minimum, include the following information and provide the information shown on Exhibit 1, Sample T&M Invoice:

- Seller's name and business address;
- Date of invoice;
- Period covered by invoice;
- This Agreement number;
- Applicable CWBS number;



- Total number of hours worked rate per hour, total labor charges, and total of all labor charges;
  - Charges for authorized materials, services, or travel; and
  - Subcontractor’s signature.
- d. Invoices shall be signed by a company officer or other responsible, authorized person and contain the following certification: “I certify to the best of my knowledge and belief that the above request for payment is true and correct; that the charges are fair and reasonable; and that the proposed request includes only allowable and allocable charges.”
- e. Subcontractor will use its best efforts to include charges on invoices no later than sixty (60) days after occurrence.
- f. All invoices are subject to audit by the Government for completeness and accuracy and for allowability of costs pursuant to Federal Acquisition Regulation (FAR) Part 31. DVC will pay only those costs ultimately determined to be allowable.

**9. Allowable Charges**

Payment to the Subcontractor for the performance of services hereunder shall be as follows:

- a. DVC shall compensate the Subcontractor for authorized work performed to address the technical intent of the Statement of Work herein, at the T&M authorized funding specified above.

**10. Security Requirements**

The Subcontractor may be required to certify that it has read and shall comply with all applicable project security requirements and that the Subcontractor has received the security clearance required for performance of the work authorized by this Agreement. If applicable, such security clearance shall remain in effect during the term of this Agreement and FAR Clause 52.204-2, Security Requirement, shall be incorporated into this Agreement by reference. Such certification shall be documented on a Training Certification issued to, and executed by, the Subcontractor before work is initiated.

**11. Agreement Supersedence**

This Agreement may be superseded in its entirety by a Task Order to be issued following execution of a Basic Ordering Agreement (BOA) between DVC and Subcontractor.

**12. Defense Priorities and Allocations System (DPAS) Rating**

This Agreement is assigned a DPAS rating of DO-C9 and contains rated order quantities certified for national defense use. The Subcontractor is required to follow all of the provisions of the Defense Priorities and Allocations System regulation (15 CFR Part 700) only as it pertains to the rated quantities.

**13. Flowdown Clauses**

- a. The clauses in Attachment F, FAR and Defense Federal Acquisition Regulation Supplement (DFARS) Flowdown Clauses, are incorporated herein by reference.
- b. Throughout this Agreement, wherever the following words are used in FAR/DFARS references, substitute the following:

<b>Government Term</b>	<b>Substitute</b>
Contract	Agreement
Contractor	Subcontractor
Subcontractor	Lower-tier Subcontractor
Government	DynPort Vaccine Company LLC
Contracting Officer	DynPort Vaccine Company LLC Subcontract Representative or designee
COTR	DynPort Vaccine Company LLC Technical Representative or designee

**14. FAR/DFARS Clauses Incorporated in Full Text**

The following FAR/DFARS clauses are incorporated herein in full text:

**52.203-11 Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (APR 1991)**

- (a) The definitions and prohibitions contained in the clause, at FAR 52.203-12, Limitation on Payments to Influence Certain Federal Transactions, included in this solicitation, are hereby incorporated by reference in paragraph (b) of this certification.
- (b) The offeror, by signing its offer, hereby certifies to the best of his or her knowledge and belief that on or after December 23, 1989 —
- (1) No Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment or modification of any Federal contract, grant, loan, or cooperative agreement;
  - (2) If any funds other than Federal appropriated funds (including profit or fee received under a covered Federal transaction) have been paid, or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or

her behalf in connection with this solicitation, the offeror shall complete and submit, with its offer, OMB standard form LLL, Disclosure of Lobbying Activities, to the Contracting Officer; and

- (3) He or she will include the language of this certification in all subcontract awards at any tier and require that all recipients of subcontract awards in excess of \$100,000 shall certify and disclose accordingly.
- (c) Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by section 1352, title 31, United States Code. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure form to be filed or amended by this provision shall be subject to a civil penalty of not less than \$10,000, and not more than \$100,000, for each such failure.

(End of clause)

**15. Intellectual Property (IP)**

- a. The IP presented in Attachment E represents the IP covering the technologies that the Subcontractor contemplates for use under this Agreement. The inventions covered by the listed patents were produced in part with Federal funding. Therefore, except for the shaded line item in Attachment E that represent non-Government funded inventions, the U.S. Government shall be granted license to practice or have practiced for or on behalf of the United States the subject invention or IP, in accordance with FAR Clause 52.227-11, Patent Rights-Retention by the Contractor (JUN 97).
- b. With regard to the shaded line items in Attachment E, which represent non-Government funded inventions, the Subcontractor shall grant DVC, for the duration of this Agreement, nonexclusive, non-transferable, irrevocable, paid-up licenses to practice the subject inventions in support of JVAP under U.S. Government Contract No. DAMD17-98-C-8024.

**16. Agreement Changes**

In accordance with Clause No. 5, Changes, of Attachment A - DVC General Terms and Conditions, DVC may modify this Agreement as required to accommodate scope, schedule, and cost changes that may arise following its execution.

**17. Special Provisions**

None identified.

IN WITNESS HEREOF, the parties have caused this Agreement to be executed.

**Accepted for:**

Subcontractor

Name: Dr. Una S. Ryan

Signature: /s/ Una S. Ryan

Title: President and CEO

Date: January 15, 2003

**Accepted for:**

DynPort Vaccine Company LLC

Name: Roy Conley

Signature: /s/ Roy Conley

Title: Senior Manager, Subcontracts

Date: January 15, 2003

SUBCONTRACT MODIFICATION				Page 1 of 1																
1. SUBCONTRACTOR SERVICE AGREEMENT NO.:  DPSC02-02257		2. EFFECTIVE DATE:  5/12/2003	3. MODIFICATION NUMBER:  03	4. MODIFICATION DATE: 5/22/2003																
5. CONTRACTOR NAME AND ADDRESS: <b>DynPort Vaccine Company LLC</b> 64 Thomas Johnson Drive Frederick, MD 21702			6. SUBCONTRACTOR NAME AND ADDRESS: <b>AVANT Immunotherapeutics, Inc.</b> 119 Fourth Avenue Needham, MA 02494-2725																	
Representatives: Contractual: Mr. Roy Conley Telephone: 301-607-5012 Technical: Dr. Barbara Solow Telephone: 301-607-5241			Representatives: Contractual: Mr. Chip Catlin Telephone: 781-433-3148 Technical: Dr. Kevin Killeen Telephone: 781-433-0771																	
7a. SUBCONTRACT MODIFICATION VALUE:			8a. REFERENCE DOCUMENTS: Prime Contract No. DAMD17-98-C-8024																	
<table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: right;">Current Value</th> <th style="text-align: right;">Increase/Decrease</th> <th style="text-align: right;">Total Value</th> </tr> </thead> <tbody> <tr> <td>Labor \$</td> <td style="text-align: right;">2,308,450.62</td> <td style="text-align: right;">1,030,911.36</td> <td style="text-align: right;">3,339,361.98</td> </tr> <tr> <td>Other Direct Costs \$</td> <td style="text-align: right;">158,877.00</td> <td style="text-align: right;">223,480.36</td> <td style="text-align: right;">382,357.36</td> </tr> <tr> <td><b>Total \$</b></td> <td style="text-align: right;"><b>2,467,327.62</b></td> <td style="text-align: right;"><b>1,254,391.72</b></td> <td style="text-align: right;"><b>3,721,719.34</b></td> </tr> </tbody> </table>				Current Value	Increase/Decrease	Total Value	Labor \$	2,308,450.62	1,030,911.36	3,339,361.98	Other Direct Costs \$	158,877.00	223,480.36	382,357.36	<b>Total \$</b>	<b>2,467,327.62</b>	<b>1,254,391.72</b>	<b>3,721,719.34</b>	8b. DPAS RATING: DO-C9	
	Current Value	Increase/Decrease	Total Value																	
Labor \$	2,308,450.62	1,030,911.36	3,339,361.98																	
Other Direct Costs \$	158,877.00	223,480.36	382,357.36																	
<b>Total \$</b>	<b>2,467,327.62</b>	<b>1,254,391.72</b>	<b>3,721,719.34</b>																	
7b. REVISED SUBCONTRACT AUTHORIZED FUNDED VALUE:			9a. AGREEMENT PERIOD OF PERFORMANCE: FROM: 12/31/2002 TO: 8/30/2004																	
<table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: right;">Prior Funded Value</th> <th style="text-align: right;">Increase/Decrease</th> <th style="text-align: right;">Revised Funded Value</th> </tr> </thead> <tbody> <tr> <td>\$</td> <td style="text-align: right;">2,467,327.62</td> <td style="text-align: right;">1,254,391.72</td> <td style="text-align: right;">3,721,719.34</td> </tr> </tbody> </table>				Prior Funded Value	Increase/Decrease	Revised Funded Value	\$	2,467,327.62	1,254,391.72	3,721,719.34	9b. AGREEMENT TYPE: Time & Materials									
	Prior Funded Value	Increase/Decrease	Revised Funded Value																	
\$	2,467,327.62	1,254,391.72	3,721,719.34																	
			9c. MODIFICATION PERIOD OF PERFORMANCE: FROM: 5/12/2003 TO: 8/30/2004																	
10. This is a <input type="checkbox"/> ADMINISTRATIVE CHANGE <input checked="" type="checkbox"/> CHANGE ORDER <input type="checkbox"/> SUPPLEMENTAL AGREEMENT																				
11. DESCRIPTION OF MODIFICATION: Modification No. 3 to Subcontractor Service Agreement No. DPSC02-02257 is hereby issued to: 1. Attachment A, Statement of Work, is incorporated herein. 2. Attachment B, Price Schedule, is incorporated herein. 3. Attachment C, Performance Schedule, is incorporated herein. 4. Charges incurred under and authorized by this Subcontract Modification shall be charged against the following Contract Work Breakdown Structure (CWBS) numbers as appropriate, which shall be referenced on all project invoices and documentation: CWBS No. C.5.9.3.1: Establish Mouse and Rabbit Models for Assessing Immunogenicity of Live Bacterial Vector Vaccines CWBS No. C.5.9.3.2: Establish Mouse Models for Immunogenicity Testing of Antigen+Alhydrogel CWBS No. C.5.9.3.3: Screen and Select Optimal Live Bacterial Vector Vaccine Candidates CWBS No. C.5.9.3.4: Demonstrate the Immunogenicity of Live Bacterial Vector Vaccines in Mice CWBS No. C.5.9.3.5: Vaccination Studies in New Zealand White Rabbits CWBS No. C.5.9.3.6: Project Management 5. All other terms and conditions of Subcontractor Service Agreement No. DPSC02-02257 remain unchanged and in full force and effect.																				
Except as provided herein, all terms and conditions of the document referenced in Block No. 1 remain unchanged and in full force and effect.																				
12. SUBCONTRACTOR: <input type="checkbox"/> IS NOT <input checked="" type="checkbox"/> IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN TWO COPIES TO THE ISSUING OFFICE.																				
13. SUBCONTRACTOR: AVANT Immunotherapeutics, Inc.			14. DynPort Vaccine Company LLC:																	
_____ /s/ Avery W. Catlin May 23, 2003 (Signature of Authorized Company Representative) & Date			_____ /s/ Roy Conley May 27, 2003 (Signature of Authorized Company Representative) & Date																	
15. NAME & TITLE OF AUTHORIZED COMPANY REPRESENTATIVE:  (Type or Print)  Avery W. Catlin, Senior Vice President and Chief Financial Officer			16. NAME & TITLE OF AUTHORIZED COMPANY REPRESENTATIVE:  Roy Conley, Senior Manager, Subcontracts																	

DynPort Vaccine Company LLC

Subcontractor Service Agreement No. DPSC03-02246

**SUBCONTRACT NO. DPSC03-02246**

This is a Time and Materials (T&M) subcontract (hereinafter referred to as "Subcontract") by and between DynPort Vaccine Company LLC (hereinafter referred to as "DVC"), a Virginia corporation, and AVANT Immunotherapeutics, Inc. (hereinafter referred to as "Subcontractor"), hereinafter referred to jointly as "the Parties".

Whereas, Subcontractor is, by reason of knowledge, education, and/or experience, capable of performing and desires to perform services for DVC in support of the U.S. Department of Defense Joint Vaccine Acquisition Program (JVAP) under U.S. Government Contract No. DAMD17-98-C-8024.

In consideration of the promises, mutual covenants, and agreements contained herein, the parties agree as follows:

**1. General Terms and Conditions**

The general conditions set forth in Attachment A, General Terms and Conditions, are incorporated herein.

**2. Scope of Work**

Subject to the terms and conditions of this Subcontract, the Subcontractor will furnish the services described in Attachment B, Statement of Work.

**3. Term**

This Subcontract shall be effective for the period July 1, 2002 through June 30, 2003. DVC may immediately terminate in the event of the Subcontractor's breach of this Subcontract, or if DVC's prime contractual support for the Subcontractor is terminated. DVC reserves the right to extend the term of this Subcontract upon written notification to, and mutual agreement of, the Subcontractor.

**4. Authorized Funding**

- a. This Subcontract has a not-to-exceed authorized funded value of \$334,257.83, in accordance with Attachment C, Price Schedule. This value represents the maximum amount the Subcontractor is currently authorized to expend in performance of the work authorized hereunder.
  - b. Subcontractor shall notify DVC's Subcontract Administrator, in writing, if Subcontractor believes that the costs which will become due to Subcontractor in the next sixty (60) days, when added to all other costs previously accrued, will exceed seventy-five percent (75%) of the authorized funding. That notice shall include an estimate of additional funds required. Subcontractor is not obligated to perform any work, and DVC is not obligated to reimburse Subcontractor for any work performed, if in performing that work Subcontractor exceeds the authorized funding.
  - c. DVC reserves the right to change the authorized funded value of this Subcontract if such change is deemed necessary by DVC to ensure the fairness and reasonableness of the authorized funded value of this Subcontract.
  - d. As required, the authorized funded value of this Subcontract will be changed by issuance of bilateral modification(s) to this Subcontract. The authorized funded value of this Subcontract shall not exceed the maximum subcontract value (ceiling value).
-

**5. Maximum Subcontract Value (Ceiling Value)**

The maximum not-to-exceed value of this Subcontract (ceiling value) shall not exceed \$334,257.83. If Subcontractor, at any time during the performance of the work authorized hereunder, has reason to believe that the ceiling value specified herein will be insufficient to complete the work, Subcontractor shall notify DVC immediately, advising the reason(s) for such cost increase and providing a revised cost estimate with supporting cost justification. The ceiling value indicated herein shall not be exceeded without DVC's prior written approval.

**6. Direction**

The Subcontractor shall be responsible for its performance. The DVC Senior Scientist, Dr. Barbara Solow, shall provide technical direction and clarification regarding the scope of work. The DVC Subcontract Administrator, Roy Conley, is solely responsible for changes/modifications to the scope, schedule, and budget of this Subcontract. No employment relationship between DVC and Subcontractor or its employees, subcontractors, or agents shall be created by this Subcontract.

**7. Consideration and Payment**

- a. As consideration for services to be provided hereunder, DVC will compensate Subcontractor per Attachment C, Price Schedule.
- b. All invoices shall be signed and dated by the Subcontractor and must reference this Subcontract number and the following Contract Work Breakdown Structure (CWBS) number:
  - CWBS No. C.5.5.4.5.3.1: Stability Testing
- c. Invoices shall be due and payable within thirty (30) days after receipt of an acceptable invoice and certification of the labor hours worked and purchases made. Invoices shall be submitted, in duplicate, to:

DynPort Vaccine Company LLC  
Attn.: Accounts Payable  
64 Thomas Johnson Drive  
Frederick, MD 21702  
Telephone: (301) 607-5000  
Fax: (301) 607-5068

Such invoice shall, at a minimum, include the following information and provide the information shown on Exhibit 1, Sample T&M Invoice:

- Subcontractor's name and business address;
- Date of invoice;
- Period covered by invoice;
- This Subcontract number;
- Applicable CWBS number;
- Total number of hours worked rate per hour, total labor charges, and total of all labor charges;
- Documentation to support the number of invoiced labor hours;
- Charges for authorized materials, services, or travel;
- Documentation to support the prices of invoiced materials, services, or travel; and
- Subcontractor's signature.

- d. Invoices shall be signed by a company officer or other responsible, authorized person and contain the following certification: "I certify to the best of my knowledge and belief that the above request for payment is true and correct; that the charges are fair and reasonable; and that the proposed request includes only allowable and allocable charges."
- e. Subcontractor will use its best efforts to include charges on invoices no later than sixty (60) days after occurrence.
- f. All invoices are subject to audit by the Government for completeness and accuracy and for allowability of costs pursuant to Federal Acquisition Regulation (FAR) Part 31. DVC will pay only those costs ultimately determined to be allowable.
- g. Subcontractor shall provide with its invoices backup documentation supporting the accuracy of all invoiced non-labor Other Direct Costs (ODCs). This documentation may include, but is not necessarily limited to, vendor invoices, vendor payment registers, etc.

**8. Allowable Charges**

Payment to the Subcontractor for the performance of services hereunder shall be as follows:

- a. DVC shall compensate the Subcontractor for authorized work performed to address the technical intent of the Statement of Work herein, at the T&M authorized funding specified above.

**9. Security Requirements**

The Subcontractor may be required to certify that it has read and shall comply with all applicable project security requirements and that the Subcontractor has received the security clearance required for performance of the work authorized by this Subcontract. If applicable, such security clearance shall remain in effect during the term of this Agreement and FAR Clause 52.204-2, Security Requirement, shall be incorporated into this Subcontract by reference. Such certification shall be documented on a Training Certification issued to, and executed by, the Subcontractor before work is initiated.

**10. Subcontract Supersedence**

At DVC's discretion, this Subcontract may be superseded in its entirety by a Task Order to be issued following execution of a Basic Ordering Agreement (BOA) between DVC and Subcontractor.

**11. Defense Priorities and Allocations System (DPAS) Rating**

This Subcontract is assigned a DPAS rating of DO-C9 and contains rated order quantities certified for national defense use. The Subcontractor is required to follow all of the provisions of the Defense Priorities and Allocations System regulation (15 CFR Part 700) only as it pertains to the rated quantities.

**12. Flowdown Clauses**

- a. The clauses in Attachment D, FAR and Defense Federal Acquisition Regulation Supplement (DFARS) Flowdown Clauses, are incorporated herein by reference.
- b. Throughout this Subcontract, wherever the following words are used in FAR/DFARS references, substitute the following:

Government Term	Substitute
Contract	Agreement
Contractor	Subcontractor
Subcontractor	Lower-tier Subcontractor
Government	DynPort Vaccine Company LLC
Contracting Officer	DynPort Vaccine Company LLC Subcontract Representative or designee
COTR	DynPort Vaccine Company LLC Technical Representative or designee

**13. FAR/DFARS Clauses Incorporated in Full Text**

The following FAR/DFARS clauses are incorporated herein in full text:

**52.203-11 Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (APR 1991)**

- (a) The definitions and prohibitions contained in the clause, at FAR 52.203-12, Limitation on Payments to Influence Certain Federal Transactions, included in this solicitation, are hereby incorporated by reference in paragraph (b) of this certification.
- (b) The offeror, by signing its offer, hereby certifies to the best of his or her knowledge and belief that on or after December 23, 1989 –
  - (1) No Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment or modification of any Federal contract, grant, loan, or cooperative agreement;
  - (2) If any funds other than Federal appropriated funds (including profit or fee received under a covered Federal transaction) have been paid, or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with this solicitation, the offeror shall complete and submit, with its offer, OMB standard form LLL, Disclosure of Lobbying Activities, to the Contracting Officer; and
  - (3) He or she will include the language of this certification in all subcontract awards at any tier and require that all recipients of subcontract awards in excess of \$100,000 shall certify and disclose accordingly.
- (c) Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by section 1352, title 31, United States Code. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure form to be filed or amended by this provision shall be subject to a civil penalty of not less than \$10,000, and not more than \$100,000, for each such failure.

(End of clause)

**14. Subcontract Changes**

In accordance with Clause No. 5, Changes, of Attachment A - DVC General Terms and Conditions, DVC may modify this Subcontract as required to accommodate scope, schedule, and cost changes that may arise following its execution.

IN WITNESS HEREOF, the parties have caused this Subcontract to be executed.

**Accepted for:**  
Subcontractor

Name: Avery W. Catlin

Signature: /s/ Avery W. Catlin

Title: Senior Vice President and CFO

Date: May 22, 2003

**Accepted for:**  
DynPort Vaccine Company LLC

Name: Roy Conley

Signature: /s/ Roy Conley

Title: Senior Manager, Subc.

Date: May 27, 2003

SECOND AMENDMENT TO  
AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS SECOND AMENDMENT TO AMENDED AND RESTATED EMPLOYMENT AGREEMENT (“Amendment”) by and between AVANT Immunotherapeutics, Inc., a Delaware corporation (f/k/a “T Cell Sciences, Inc.,” the “Company”) and Una S. Ryan, Ph.D. (the “Executive”), is dated as of September 18, 2003.

WHEREAS, the Company and the Executive entered into an Employment Agreement as of May 28, 1996 (the “Original Agreement”);

WHEREAS, the Company and the Executive entered into an Amended and Restated Employment Agreement as of August 20, 1998 (the “Employment Agreement”), which Employment Agreement amended, restated and superseded the Original Agreement;

WHEREAS, the Employment Agreement was amended by the First Amendment to the Amended and Restated Employment Agreement dated December 23, 2002; and

WHEREAS, the parties agree to further amend certain provisions of the Employment Agreement in accordance with Section 19 thereof.

NOW, THEREFORE, the Company and the Executive, each intending to be legally bound hereby, do mutually covenant and agree as follows:

1. Section 6(f) of the Employment Agreement is hereby amended by deleting said Section in its entirety and substituting therefor the following:

**“f. Termination Benefits On or After Change in Control.**

(i) In the event of termination of the Executive’s employment with the Company pursuant to Section 6(c) or 6(d) above on or after a Change in Control, the Company shall pay to the Executive an aggregate amount equal to (a) three (3) times the “base amount” (as defined in Section 280G(b)(3) of the Internal Revenue Code of 1986, as amended (the “Code”)) applicable to the Executive, less (b) One Dollar (\$1.00), payable in one lump sum in cash on the date of such termination.

(ii) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (the “Severance Payments”), would be subject to the excise tax imposed by Section 4999 of the Code, or any interest or penalties are incurred

---



by the Executive with respect to such excise tax (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then the Executive shall be entitled to receive an additional payment (a "Gross-Up Payment") such that the net amount retained by the Executive, after deduction of any Excise Tax on the Severance Payments, any Federal, state, and local income tax, employment tax and Excise Tax upon the payment provided by this subsection, and any interest and/or penalties assessed with respect to such Excise Tax, shall be equal to the Severance Payments.

(iii) Subject to the provisions of Subparagraph 6(f)(iv), all determinations required to be made under this Subparagraph 6(f)(iii), including whether a Gross-Up Payment is required and the amount of such Gross-Up Payment, shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Executive within fifteen (15) business days of the date of termination of the Executive's employment, if applicable, or at such earlier time as is reasonably requested by the Company or the Executive. For purposes of determining the amount of the Gross-Up Payment, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the Gross-Up Payment is to be made, and state and local income taxes at the highest marginal rates of individual taxation in the state and locality of the Executive's residence on the date of termination of the Executive's employment, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes. The initial Gross-Up Payment, if any, as determined pursuant to this Subparagraph 6(f)(iii), shall be paid to the Executive within five (5) days of the receipt of the Accounting Firm's determination. If the Accounting Firm determines that no Excise Tax is payable by the Executive, the Company shall furnish the Executive with an opinion of counsel that failure to report the Excise Tax on the Executive's applicable federal income tax return would not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made (an "Underpayment"). In the event that the Company exhausts its remedies pursuant to Subparagraph 6(f)(iv) and the Executive thereafter is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred, consistent with the calculations required to be made hereunder, and any such Underpayment, and any interest and penalties imposed on the Underpayment and required to be paid by the Executive in connection with the proceedings described in Subparagraph 6(f)(iv), shall be promptly paid by the Company to or for the benefit of the Executive.

(iv) The Executive shall notify the Company in writing of any claim by the Internal Revenue Service that, if successful, would require the payment by the Company of the Gross-up Payment. Such notification shall be given as soon as practicable but no later than ten (10) business days after the Executive knows of such claim and shall apprise the Company of the nature of such claim and the date on which such claim is requested to be paid. The Executive shall not pay such claim prior to the expiration of the 30-day period following the date on which he gives such notice to the Company (or such shorter period ending on the date that any payment of taxes with respect to such claim is due). If the Company notifies the Executive in writing prior to the expiration of such period that it desires to contest such claim, provided that the Company has set aside adequate reserves to cover the Underpayment and any interest and penalties thereon that may accrue, the Executive shall:

(A) give the Company any information reasonably requested by the Company relating to such claim,

(B) take such action in connection with contesting such claim as the Company shall reasonably request in writing from time to time, including, without limitation, accepting legal representation with respect to such claim by an attorney selected by the Company,

(C) cooperate with the Company in good faith in order to effectively contest such claim, and

(D) permit the Company to participate in any proceedings relating to such claim; provided, however, that the Company shall bear and pay directly all costs and expenses (including additional interest and penalties) incurred in connection with such contest and shall indemnify and hold the Executive harmless, on an after-tax basis, for any Excise Tax or income tax, including interest and penalties with respect thereto, imposed as a result of such representation and payment of costs and expenses. Without limitation on the foregoing provisions of this Subparagraph 6(f)(iv), the Company shall control all proceedings taken in connection with such contest and, at its sole option, may pursue or forego any and all administrative appeals, proceedings, hearings and conferences with the taxing authority in respect of such claim and may, at its sole option, either direct the Executive to pay the tax claimed and sue for a refund or contest the claim in any permissible manner, and the Executive agrees to prosecute such contest to a determination before any administrative tribunal, in a court of initial jurisdiction and in one or more appellate courts, as the Company shall determine; provided, however, that if the Company directs the Executive to pay such claim and sue for a refund, the Company shall advance the amount of such payment to the Executive on an interest-free basis and shall indemnify and hold the Executive harmless, on an after-tax basis, from any

Excise Tax or income tax, including interest or penalties with respect thereto, imposed with respect to such advance or with respect to any imputed income with respect to such advance; and further provided that any extension of the statute of limitations relating to payment of taxes for the taxable year of the Executive with respect to which such contested amount is claimed to be due is limited solely to such contested amount. Furthermore, the Company's control of the contest shall be limited to issues with respect to which a Gross-Up Payment would be payable hereunder and the Executive shall be entitled to settle or contest, as the case may be, any other issues raised by the Internal Revenue Service or any other taxing authority.

(v) If, after the receipt by the Executive of an amount advanced by the Company pursuant to Subparagraph 6(f)(iv), the Executive becomes entitled to receive any refund with respect to such claim, the Executive shall (subject to the Company's complying with the requirements of Subparagraph 6(f)(iv)) promptly pay to the Company the amount of such refund (together with any interest paid or credited thereon after taxes applicable thereto). If, after the receipt by the Executive of an amount advanced by the Company pursuant to Subparagraph 6(f)(iv), a determination is made that the Executive shall not be entitled to any refund with respect to such claim and the Company does not notify the Executive in writing of its intent to contest such denial of refund prior to the expiration of 30 days after such determination, then such advance shall be forgiven and shall not be required to be repaid and the amount of such advance shall offset, to the extent thereof, the amount of Gross-Up Payment required to be paid.

(vi) If any dispute between the Company and the Executive as to any of the amounts to be determined under this subsection (f), or the method of calculating such amounts, cannot be resolved by the Company and the Executive, either the Company or the Executive after giving three days' written notice to the other, may refer the dispute to a partner in the Boston office of a firm of independent certified public accountants selected jointly by the Company and the Executive. The determination of such partner as to the amount to be determined under this subsection (f) and the method of calculating such amounts shall be final and binding on both the Company and the Executive. The Company shall bear the costs of any such determination."

2. Except as so amended, the Employment Agreement in all other respects is hereby confirmed.

IN WITNESS WHEREOF, this Amendment has been executed as a sealed instrument by the Company, by its duly authorized officer, and by the Executive, as of the date first written herein above.

AVANT IMMUNOTHERAPEUTICS, INC.

By:     /s/ J. Barrie Ward      
J. Barrie Ward, Director

    /s/ Una S. Ryan      
Executive

RESTRICTED STOCK UNIT AGREEMENT  
 UNDER THE AVANT IMMUNOTHERAPEUTICS, INC.  
 1999 STOCK OPTION AND INCENTIVE PLAN

Name of Grantee: Una S. Ryan, Ph.D.  
 No. of Restricted Stock Units Granted: 400,000  
 Grant Date: September 18, 2003

Pursuant to the AVANT Immunotherapeutics, Inc. 1999 Stock Option and Incentive Plan (the "Plan") as amended through the date hereof, AVANT Immunotherapeutics, Inc. (the "Company") hereby grants a deferred stock award consisting of the number of Restricted Stock Units listed above (an "Award") to the Grantee named above. Each "Restricted Stock Unit" shall relate to one share of Common Stock, par value \$.001 per share (the "Stock") of the Company specified above, subject to the restrictions and conditions set forth herein and in the Plan.

1. Acceptance of Award. The Grantee shall have no rights with respect to this Award unless she shall have accepted this Award within 90 days of receipt hereof by signing and delivering to the Company a copy of this Award Agreement. Any consideration due to the Company on the issuance of the Award has been deemed to be satisfied by past services rendered by the Grantee to the Company.

2. Restrictions on Transfer of Award. The Award shall not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, until (i) the Restricted Stock Units have vested as provided in Section 3 of this Agreement, (ii) the Deferral Period has expired, and (iii) a certificate has been issued pursuant to Section 6 of this Agreement.

3. Vesting of Restricted Stock Units. The Restricted Stock Units shall vest in accordance with the schedule set forth below, provided in each case that the Grantee is then, and since the Grant Date has continuously been, employed by the Company or its Subsidiaries.

Incremental (Aggregate) Number of Restricted Stock Units Vested	Vesting Date
100,000 (100,000)	July 17, 2004
100,000 (200,000)	July 17, 2005
100,000 (300,000)	July 17, 2006
100,000 (400,000)	July 17, 2007

The Administrator may at any time accelerate the vesting schedule specified in this Paragraph 3. Notwithstanding the foregoing, the Grantee shall become vested in the Restricted Stock Units prior to the Vesting Date set forth above in the following circumstances:

---

(a) Immediately prior to the consummation of a Change of Control, all Restricted Stock Units that have not previously been forfeited shall immediately vest; provided that the Grantee is then employed by the Company or its Subsidiaries.

(b) In the event of the Grantee's employment terminates on account of death or disability, all Restricted Stock Units that have not previously been forfeited shall immediately vest.

(c) In the event the Grantee's employment is terminated by the Company without Cause, all Restricted Stock Units that have not previously been forfeited shall immediately vest. For purposes hereof, "Cause" shall have the same meaning as set forth in the Amended and Restated Employment Agreement between the Company and the Grantee dated August 20, 1998, as amended from time to time.

4. Forfeiture. In the event the Company terminates the Grantee's employment for Cause or the Grantee terminates her employment on her own initiative (it being understood that in this context, a termination of employment on the Grantee's own initiative does not include a termination due to her death or disability), all Restricted Stock Units that have not previously been forfeited on such date shall be immediately forfeited to the Company.

5. Dividend Equivalents.

(a) If on any date the Company shall pay any dividend on shares of Stock of the Company, the number of Restricted Stock Units credited to the Grantee shall, as of such date, be increased by an amount determined by the following formula:

$W = (X \text{ multiplied by } Y) \text{ divided by } Z$ , where:

W = the number of additional Restricted Stock Units to be credited to the Grantee on such dividend payment date;

X = the aggregate number of Restricted Stock Units (whether vested or unvested) credited to the Grantee as of the record date of the dividend;

Y = the cash dividend per share amount; and

Z = the Fair Market Value per share of Stock (as determined under the Plan) on the dividend payment date.

(b) In the case of a dividend paid on Stock in the form of Stock, including without limitation a distribution of Stock by reason of a stock dividend, stock split or otherwise, the number of Restricted Stock Units credited to the Grantee shall be increased by a number equal to the product of (i) the aggregate number of Restricted Stock Units that have been awarded to the Grantee through the related dividend record date, and (ii) the number of shares of Stock (including any fraction thereof) payable as dividend on one share of Stock. In the case of a dividend payable in property other than shares of Stock or cash, the per share of Stock value of such dividend shall be determined in good faith by the Board of Directors of the Company and shall be converted to additional Restricted Stock Units based on the formula in (a) above. Any

additional Restricted Stock Units shall be subject to the vesting and restrictions of this Agreement in the same manner and for so long as the Restricted Stock Units granted pursuant to this Agreement to which they relate remain subject to such vesting and restrictions, and shall be promptly forfeited to the Company if and when such Restricted Stock Units are so forfeited.

6. Receipt of Shares of Stock.

(a) As soon as practicable following the date the Grantee terminates employment with the Company or its Subsidiaries (the "Deferral Period"), the Company shall issue to the Grantee a certificate representing the number of shares of Stock equal to the aggregate number of Restricted Stock Units credited to the Grantee that have vested pursuant to Section 3 of this Agreement on such date in full satisfaction of such Restricted Stock Units.

(b) Upon a Change of Control, the Company shall issue to the Grantee a certificate representing the number of shares of Stock equal to the aggregate number of Restricted Stock Units credited to the Grantee on such date (determined after giving effect to Section 3(a) above) in full satisfaction of such Restricted Stock Units; provided, however, that in the event the Company is involved in a transaction in which shares of Stock will be exchanged for cash or other consideration, the Company shall issue to the Grantee immediately prior to the consummation of such transaction a certificate representing the number of shares of Stock equal to the aggregate number of Restricted Stock Units credited to the Grantee on such date (determined after giving effect to Section 3(a) above).

(c) In each instance above, the certificate or certificates issued to the Grantee covering the shares of Stock shall be subject to the payment by the Grantee by cash or other means acceptable to the Company of any federal, state, local and other applicable taxes required to be withheld in connection with such issuance in accordance with Section 9 of this Agreement. The Grantee understands that once a certificate has been delivered to the Grantee in respect of the Restricted Stock Units, the Grantee will be free to sell the shares of Stock evidenced by such certificate, subject to applicable requirements of federal and state securities laws. Immediately after the issuance of shares of Stock, this Agreement shall terminate and be of no further force or effect.

7. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

8. Transferability of this Agreement. This Agreement is personal to the Grantee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution.

9. Tax Withholding. The Grantee shall, not later than the date as of which the receipt of this Award becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The

Grantee may elect to have the required minimum tax withholding obligation satisfied, in whole or in part, by (i) authorizing the Company to withhold from shares of Stock to be issued, or (ii) transferring to the Company, a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due.

10. Miscellaneous.

(a) Notice hereunder shall be given to the Company at its principal place of business, and shall be given to the Grantee at the address set forth below, or in either case at such other address as one party may subsequently furnish to the other party in writing.

(b) This Agreement does not confer upon the Grantee any rights with respect to continuation of employment by the Company or any Subsidiary.

AVANT IMMUNOTHERAPEUTICS, INC.

By: /s/ J. Barrie Ward  
J. Barrie Ward, Director

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned.

Dated: September 18, 2003

/s/ Una S. Ryan  
Grantee's Signature

Grantee's name and address:

Una S. Ryan

329 Hammond St.

Chestnut Hill, MA 02467



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 6, 2003

By: /s/ Una S. Ryan  
Name: Una S. Ryan, Ph.D.  
Title: President and Chief Executive Officer

CERTIFICATION

I, Avery W. Catlin, certify that:

6. I have reviewed this report on Form 10-Q of AVANT Immunotherapeutics, Inc.;
7. 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;
8. 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;
9. 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
10. 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 6, 2003

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 6, 2003

By: /s/ Una S. Ryan  
Name: Una S. Ryan, Ph.D.  
Title: President and Chief Executive Officer

Date: November 6, 2003

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