

**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 March 31, 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 12.6-2 of the Exchange Act.)
Yes No .

As of May 8, 2003, 60,468,690 shares of common stock, \$.001 par value per share, were outstanding.

AVANT IMMUNOTHERAPEUTICS, INC.

FORM 10-Q
Quarter Ended March 31, 2003
Table of Contents

Part I — Financial Information

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

[Consolidated Statement of Operations for the Three Months Ended March 31, 2003 and 2002](#)

[Consolidated Statement of Cash Flows for the Three Months Ended March 31, 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](#)

[Signatures](#)

[Certifications](#)

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

**AVANT IMMUNOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEET
March 31, 2003 and December 31, 2002**

	<u>March 31, 2003</u>	<u>December 31, 2002</u>
	<u>(unaudited)</u>	
ASSETS		
Current Assets:		
Cash and Cash Equivalents	\$ 19,750,400	\$ 25,070,700
Accounts Receivable	634,500	230,900
Prepaid Expenses and Other Current Assets	<u>536,500</u>	<u>558,400</u>
Total Current Assets	<u>20,971,400</u>	<u>25,860,000</u>
Property and Equipment, Net	1,114,000	1,119,500
Intangible and Other Assets	8,948,200	7,217,400
Goodwill	<u>1,036,300</u>	<u>1,036,300</u>
Total Assets	<u>\$ 32,019,900</u>	<u>\$ 35,233,200</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 349,000	\$ 836,000
Accrued Expenses	1,904,100	2,098,900
Current Portion Deferred Revenue	<u>1,535,200</u>	<u>497,700</u>
Total Current Liabilities	<u>3,788,300</u>	<u>3,432,600</u>
Long-Term Deferred Revenue	331,800	456,200
Stockholders' Equity:		
Common Stock, \$.001 Par Value; 100,000,000 Shares Authorized; 60,468,700 Issued and 60,253,400 Outstanding at March 31, 2003 and 60,464,900 Issued and 60,332,300 Outstanding at December 31, 2002	60,500	60,500
Additional Paid-In Capital	223,326,300	223,322,900
Less: 215,300 and 132,600 Common Treasury Shares at Cost at March 31, 2003 and December 31, 2002	(222,300)	(136,400)
Accumulated Deficit	<u>(195,264,700)</u>	<u>(191,902,600)</u>
Total Stockholders' Equity	<u>27,899,800</u>	<u>31,344,400</u>
Total Liabilities and Stockholders' Equity	<u>\$ 32,019,900</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 March 31, 2003 and 2002
(Unaudited)**

	<u>March 31, 2003</u>	<u>March 31, 2002</u>
REVENUE:		
Product Development and Licensing Agreements	\$ 169,400	\$ 585,300
Government Contract Revenue	477,000	¾
Product Royalties	35,300	¾
Product Sales	<u>¾</u>	<u>105,600</u>
Total Revenue	<u>681,700</u>	<u>690,900</u>

OPERATING EXPENSE:		
Research and Development	2,692,500	4,409,600
Selling, General and Administrative	1,224,700	1,185,900
Cost of Product Sales	¾	13,700
Amortization of Acquired Intangible Assets	248,800	198,800
Total Operating Expense	4,166,000	5,808,000
Operating Loss	(3,484,300)	(5,117,100)
Investment Income, Net	122,100	203,500
Net Loss	\$ (3,362,200)	\$ (4,913,600)
Basic and Diluted Net Loss Per Common Share	\$ (0.06)	\$ (0.08)
Weighted Average Common Shares Outstanding	60,468,600	60,457,400

See accompanying notes to unaudited consolidated financial statements

4

AVANT IMMUNOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
For the Three Months Ended March 31, 2003 and 2002
(Unaudited)

	March 31, 2003	March 31, 2002
Cash Flows from Operating Activities:		
Net Loss	\$ (3,362,200)	\$ (4,913,600)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	435,100	429,300
Changes in Assets and Liabilities:		
Accounts Receivable	(403,600)	39,700
Inventories	¾	12,100
Prepaid and Other Current Assets	21,900	(82,400)
Increase in Other Assets	¾	(13,400)
Accounts Payable and Accrued Expenses	(681,800)	(483,500)
Deferred Revenue	913,100	(397,300)
Net Cash Used in Operating Activities	(3,077,500)	(5,409,100)
Cash Flows from Investing Activities:		
Acquisition of Property and Equipment	(100,400)	(185,200)
Increase in Patents and Licenses	(59,900)	(52,500)
Cash Paid for Acquisition of Universal Preservation Technologies, Inc. Assets	(2,000,000)	¾
Net Cash Used in Investing Activities	(2,160,300)	(237,700)
Cash Flows from Financing Activities:		
Proceeds from Exercise of Stock Options and Warrants	3,400	35,100
Purchases of Treasury Stock	(85,900)	¾
Net Cash (Used In) Provided by Financing Activities	(82,500)	35,100
Decrease in Cash and Cash Equivalents	(5,320,300)	(5,611,700)
Cash and Cash Equivalents at Beginning of Period	25,070,700	42,665,900
Cash and Cash Equivalents at End of Period	\$ 19,750,400	\$ 37,054,200

See accompanying notes to unaudited consolidated financial statements

5

AVANT IMMUNOTHERAPEUTICS, INC.
Notes to Consolidated Financial Statements
March 31, 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 ended March 31, 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 positions at March 31, 2003, the results of operations for the quarters ended March 31, 2003 and 2002, and the cash flows for the three months ended March 31, 2003 and 2002. The results of operations for the quarter ended March 31, 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 July 2002, the FASB issued SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized at its fair market value when the liability is incurred, rather than at the date of an entity's commitment to an exit plan. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 has not had a material effect on the Company's financial statements.

In December 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure" ("SFAS 148"). SFAS 148 provides alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation as originally provided by SFAS No. 123 "Accounting for Stock-Based Compensation". Additionally, SFAS 148 amends the disclosure requirements of SFAS 123 to require prominent disclosure in both the annual and interim financial statements about the method of accounting for stock-based compensation and the effect of the method used on reported results. The transitional requirements of SFAS 148 will be effective for all financial statements for fiscal years ending after December 15, 2002. The disclosure requirements shall be effective for financial reports

6

containing condensed financial statements for interim periods beginning after December 15, 2002. We adopted this statement as of December 31, 2002 and have included the appropriate disclosure herein. The application of SFAS 148 has not had a material impact on our financial statements.

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 or modified, during the first quarter of fiscal 2003. The adoption of FIN No. 45 did not have a material effect on our consolidated financial statements. The following is a summary of our agreements, that we have determined are 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 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 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 to new entities that are created after the effective date, as well as to existing entities. The FIN applies to preexisting entities as of the beginning of the first interim period beginning after June 15, 2003, and to any new entities beginning February 1, 2003. Once it becomes effective, 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.

(4) Property and Equipment

Property and equipment includes the following:

March 31, 2003	December 31, 2002
-------------------	----------------------

Laboratory Equipment	\$	2,390,500	\$	2,323,800
Office Furniture and Equipment		1,606,500		1,577,500
Leasehold Improvements		1,617,400		1,612,600
Property and Equipment, Total		5,614,400		5,513,900
Less Accumulated Depreciation and Amortization		(4,500,400)		(4,394,400)
	\$	1,114,000	\$	1,119,500

7

(5) **Intangible and Other Assets**

Intangible and other assets include the following:

	Estimated Lives	March 31, 2003	December 31, 2002
Capitalized Patent Costs	10 years	\$ 2,803,500	\$ 2,743,600
Accumulated Amortization		(1,648,700)	(1,568,300)
Capitalized Patent Costs, Net		1,154,800	1,175,300
Acquired Intangible Assets:			
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		(2,995,200)	(2,746,500)
Acquired Intangible Assets, Net		7,708,700	5,957,400
Other Non Current Assets		84,700	84,700
		\$ 8,948,200	\$ 7,217,400

All of our intangible assets are amortized over their useful lives. Total amortization expense for intangible assets was \$248,700 and \$198,800 for the three-month periods ended March 31, 2003 and March 31, 2002, respectively.

The estimated future amortization expense of intangible assets as of March 31, 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 nine months)	\$ 746,400
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 periods ended March 31, 2003 and 2002 as its inclusion would have been anti-dilutive. A total of 5,201,900 and 5,117,700 stock options and warrants were excluded from the computation of weighted average common shares as of March 31, 2003 and 2002, respectively, as they were anti-dilutive.

8

(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 March 31,	
	2003	2002
Net Loss:		
As reported	\$ 3,362,200	\$ 4,913,600
Less: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(226,100)	(280,200)
Pro forma	3,588,300	5,193,800

Basic and Diluted Net Loss Per Share:

As reported	\$	0.06	\$	0.08
Pro forma		0.06		0.09

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 March 31,	
	2003	2002
Expected stock price volatility	109%	109%
Expected option term	2.5 Years	2.5 Years
Risk-free interest rate	1.2 - 1.6%	2.5 - 3.5%
Expected dividend yield	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.

(7) 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 Company purchased 215,300 shares through March 31, 2003 at a cost of \$222,300. Approximately 1,784,700 shares remain authorized for repurchase under this program at December 31, 2002.

(8) 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 this technology has alternative future uses and will be incorporated into a number of the 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.

(9) Subcontract 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. AVANT expects to execute additional subcontracts with DVC. Under the agreement, AVANT may receive in excess of \$8 million over a two-year period, covering vaccine development through preclinical testing.

(10) 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 at the fair market value on the day granted. 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.

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 ability to integrate the UPT technology 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; (3) the ability to successfully complete development and commercialization of CholeraGarde[®] (Peru-15), Ty800, CETi-1 and of other products; (4) the cost, timing, scope and results of ongoing safety and efficacy trials of 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 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) the volume and profitability of product sales of Megan®Vac 1 and other future products; (8) changes in existing and potential relationships with corporate collaborators; (9) the cost, delivery and quality of clinical and commercial grade materials supplied by contract manufacturers (10) the timing, cost and uncertainty of obtaining regulatory approvals to use 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; (11) the ability to obtain substantial additional funding; (12) the ability to develop and commercialize products before competitors; (13) the integration of Megan Health's business and programs; (14) the ability to retain certain members of management; and (15) other factors detailed from time to time in filings with the Securities and Exchange Commission. In addition, the factors described under "Risk Factors" in this report may result in these differences. 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 has not acquired UPT's San Diego facility or employees in this transaction. We have determined that this technology has alternative future uses and will be incorporated into a number of AVANT's bacterial vaccine programs. AVANT paid an aggregate of \$2,000,000 in consideration in the transaction, recorded this value to acquired intangible assets and is amortizing these assets over their estimated lives of ten years.

Megan Health, Inc.: On December 1, 2000, AVANT acquired all of the outstanding capital stock of Megan Health, Inc. ("Megan"), a company engaged in the discovery and development of human and animal vaccines using patented gene modification technologies. In connection with the acquisition, we recorded a charge of \$9,012,300 for acquired in-process research and development ("IPR&D"), which represented purchased in-process technology which had not yet reached technological feasibility and had no alternative future use. 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

PROGRAM DEVELOPMENTS

Rotavirus Vaccine: Rotavirus is a major cause of diarrhea and vomiting in infants and children. No vaccine against rotavirus is currently on the market. In 1997, 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. Glaxo has initiated Phase I/II bridging studies in Europe, Latin America and Asia using its newly manufactured, two-dose oral rotavirus vaccine, called Rotarix™. AVANT expects Glaxo to initiate global Phase III clinical trials of Rotarix™ in the second half of 2003. Assuming product development and commercialization continues satisfactorily, we may receive additional milestone payments upon the achievement of specified milestones. In addition, we will be entitled to royalties based on net sales of Rotarix™.

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. 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.

These data were extremely helpful in moving the program forward to a placebo controlled Phase II study, which was initiated in August 2001, in approximately 200 patients with low levels of HDL cholesterol. The objectives of the study are 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 is the change in HDL cholesterol measured after the six-month booster. Results are expected from the trial during the fourth quarter of 2003. 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 trials in December 2002 with the International Vaccine Institute (IVI) in Bangladesh where cholera is endemic. 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. Finally, we are developing three additional bacterial vaccines against enterotoxigenic *E. coli*, *Shigella* and *Campylobacter* — all important causes of serious diarrheal diseases worldwide.

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 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 advance 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 the Walter Reed Army Institute of Research (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 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 over a twelve-month period.

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 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. AVANT expects to execute additional subcontracts with DVC. Under the agreement, AVANT may receive in excess of \$8 million over a two-year period, covering vaccine development through preclinical testing.

AVANT is leveraging the value of its vaccine technologies into additional markets through key collaborations. In addition to our arrangements with DVC and the NIAID to develop new generations of anthrax and plague vaccines using our vectoring technologies and with IVI to bring our bacterial vaccines to developing countries where they are most needed, 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.

Modern biotechnology offers great potential for bettering health conditions worldwide. New vaccine technologies, in particular, can provide avenues to disease prevention and treatment with notable advantages over drugs in terms of patient compliance and cost. They also offer strategies to solve global health problems, to protect both civilians and military from biowarfare threats, and to increase the safety of our food supply. Our goal is to become a leading developer of innovative vaccines that address health care needs on a global basis. In this regard, 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, 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.

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

14

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.

Based on the outcomes of an adult TP10 clinical trial in which TP10 failed to meet the trial's primary endpoint, AVANT no longer plans to advance clinical development of the complement inhibitor program on its own or to invest a significant amount of its own resources into the development of this program going forward. Instead, we plan to seek partnering arrangements to capture the value inherent in this program and its strong intellectual property. With the termination of the Novartis agreement, AVANT can now offer a worldwide license for all fields, which we believe improves the likelihood of a partnership arrangement.

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. We see this licensing opportunity as an excellent way to further leverage our vaccine technology.

RESULTS OF OPERATIONS

Three Month Period Ended March 31, 2003 as Compared With the Three Month Period Ended March 31, 2002

AVANT reported consolidated net loss of \$3,362,200, or \$.06 per share, for the first quarter ended March 31, 2003, compared with a net loss of \$4,913,600, or \$.08 per share, for the first quarter ended March 31, 2002. The weighted average common shares outstanding used to calculate net loss per common share was 60,468,600 in 2003 and 60,457,400 in 2002.

Revenue: Total revenue decreased \$9,200, or 1.3%, to \$681,700 for the first quarter of 2003 compared to \$690,900 for the first quarter of 2002.

Product development and licensing revenue decreased \$415,900, or 71.1%, to \$169,400 in 2003 from \$585,300 in 2002. In 2003, product development and licensing revenue consisted primarily of \$124,400 for the amortization of nonrefundable license fees from Pfizer, \$10,000 in funded research from Pfizer, \$12,500 in license fee from DynPort and \$22,500 received in connection with government grants. In 2002, product development and licensing revenue consisted primarily of \$384,900 for the amortization of nonrefundable license fees from Novartis and Pfizer, \$125,000 in funded research from Pfizer, \$37,500 in license fee and milestone payments from DynPort and \$37,900 received in connection with government grants.

In January 2003, AVANT was awarded a new Department of Defense subcontract from its partner, DVC, that supports the development of an oral, combination vaccine against both anthrax and plague using

15

our vectored vaccine technology. AVANT will be reimbursed by DVC on a time and materials basis for vaccine development research work performed by AVANT in the amount of \$2.5 million. Under the agreement, AVANT recognized \$477,000 in government contract revenue during the first 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 first quarter of 2003 AVANT received a percentage of all Megan®Vac 1 product sales as product royalty payments totaling \$35,300. Product sales for the first quarter of 2002 totaled \$105,600 and were derived from sales of the Megan®Vac 1 product, a vaccine for use in chickens for protection against multiple strains of *Salmonella* bacteria, which we acquired in connection with our acquisition of Megan.

Operating Expense: Total operating expense decreased \$1,642,000, or 28.3%, to \$4,166,000 for the first quarter of 2003 compared to \$5,808,000 for the first quarter of 2002. The decrease in total operating expense for 2003 compared to 2002 primarily results from a reduction in research and development expense in the first quarter of 2003 due to decreased clinical trials costs of \$568,200 related to a decline in the number of clinical trials being conducted by AVANT during the quarter and a reduction in contract manufacturing and consulting costs of \$1,302,200 associated with the bacterial vaccines programs.

Research and development expense decreased \$1,717,100, or 38.9%, to \$2,692,500 in 2003 from \$4,409,600 in 2002. The decrease in 2003 compared to 2002 is primarily due to a decrease in the number of clinical trials and a reduction in expense associated with the manufacture of clinical materials for the bacterial vaccines programs, as during the first quarter of 2003 there was limited contract manufacturing activity due to delays in production runs. The decrease in research and development expense further resulted from declines in personnel and related expenses, sponsored research and manufacturing consultancy costs, offset in part by increases in license fees and facility-related costs.

Selling, general and administrative expense increased \$38,800, or 3.3%, to \$1,224,700 in 2003 compared to \$1,185,900 in 2002. The increase in expense in 2003 compared to 2002 is primarily attributed to an increase in legal expenses, insurance expenses and facility-related costs, offset in part by a decrease in selling and marketing expense in 2003 and in personnel and related costs and consultancy costs.

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

Investment Income, Net: Interest income decreased \$81,400, or 40%, to \$122,100 for the first quarter of 2003 compared to \$203,500 for the first quarter of 2002. The decrease is primarily due to lower interest rates and lower average cash balances during the first quarter of 2003 compared to the first quarter of 2002.

LIQUIDITY AND CAPITAL RESOURCES

AVANT ended the first quarter of 2003 with cash and cash equivalents of \$19,750,400 compared to cash and cash equivalents of \$25,070,700 at December 31, 2002.

Net cash used in operating activities decreased to \$3,077,500 for the first three months of 2003 compared to \$5,409,100 for the first three months of 2002. The decrease is primarily attributed to the decrease in net loss incurred in 2003 compared to 2002 and an increase in deferred revenue.

Net cash used in investing activities increased to \$2,160,300 for the first three months of 2003 compared to \$237,700 for the first three months of 2002. The increase is primarily due to \$2 million of cash paid for certain assets of Universal Preservation Technologies, Inc.

Net cash used in financing activities was \$82,500 for the first three months of 2003 compared to net cash provided by financing activities of \$35,100 for the first three months of 2002. The decrease is due

to a decrease in proceeds from the exercise of stock options and warrants, coupled with the purchases of treasury stock under a share repurchase plan.

As of March 31, 2003, AVANT had future payments required under contractual obligations and other commitments approximately as follows:

	<u>Total</u>	<u>Less than One Year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>
Operating lease obligations	\$ 8,953,200	\$ 1,743,900	\$ 6,499,600	\$ 709,700
Licensing obligations	912,000	447,000	275,000	190,000
Total future obligations	<u>\$ 9,865,200</u>	<u>\$ 2,190,900</u>	<u>\$ 6,774,600</u>	<u>\$ 899,700</u>

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 March 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 March 31, 2003 and December 31, 2002 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

(a) *Evaluation of disclosure controls and procedures.*

As required by new 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

17

Commission's rules and forms. In connection with the new rules, we will continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, 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.

(b) *Changes in internal controls.*

None.

PART II — OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) **Exhibits**

None

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

A Form 8-K (Item 5) was filed on March 10, 2003 regarding a press release announcing the acquisition of intellectual property from Pharmacia Corporation.

18

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: May 12, 2003

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

Dated: May 12, 2003

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

19

Certification

I, Una S. Ryan, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AVANT Immunotherapeutics, Inc.;

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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-14 and 15d-14) for the registrant and we have:
- a. designed such disclosure controls and procedures 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 quarterly report is being prepared;
 - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
- a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 12, 2003

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

20

Certification

I, Avery W. Catlin, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of AVANT Immunotherapeutics, Inc.;
- 2. Based on my knowledge, this quarterly 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 quarterly report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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-14 and 15d-14) for the registrant and we have:
 - d. designed such disclosure controls and procedures 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 quarterly report is being prepared;
 - e. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - f. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - c. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - d. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 12, 2003

/s/ Avery W. Catlin
Avery W. Catlin
Senior Vice President and

