## 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, 2005

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** 

No. 13-3191702

(State of Incorporation)

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

119 Fourth Avenue, Needham, Massachusetts 02494-2725

(Address of principal executive offices) (Zip Code)

(781) 433-0771

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12 b-2 of the Exchange Act.)

Yes 
No o.

As of May 3, 2005, 74,132,829 shares of common stock, \$.001 par value per share, were outstanding.

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## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements

# AVANT IMMUNOTHERAPEUTICS, INC. CONSOLIDATED BALANCE SHEETS (Unaudited)

	March 31, 			December 31, 2004
ASSETS				
Current Assets:				
Cash and Cash Equivalents	\$	27,309,120	\$	31,741,494
Accounts Receivable		916,451		2,230,350
Prepaid Expenses and Other Current Assets		668,745		567,916
Total Current Assets		28,894,316		34,539,760
Property and Equipment, Net		4,430,436		4,164,292
Intangible and Other Assets		5,813,407		6,063,185
Goodwill		1,036,285		1,036,285
Total Assets	\$	40,174,444	\$	45,803,522
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts Payable	\$	1,136,158	\$	1,752,313
Accrued Expenses		3,237,668		3,500,422
Current Portion of Deferred Revenue		37,499		11,704
Current Portion of Long-Term Liabilities		186,509		186,509
Total Current Liabilities		4,597,834		5,450,948
Long-Term Liabilities		1,914,001		1,944,948
Stockholders' Equity:				
Convertible Preferred Stock, 4,513,102 Shares Authorized; None Issued and Outstanding		_		_
Common Stock, \$.001 Par Value; 100,000,000 Shares Authorized; 74,353,148 Issued and 74,132,829 Outstanding at March 31, 2005 and 74,351,571 Issued and 74,131,252 Outstanding at December 31,				
2004		74,353		74,351
Additional Paid-In Capital		257,832,304		257,829,824
Deferred Compensation		(1,372,000)		(1,493,000)
Less: 220,319 Common Treasury Shares at Cost		(227,646)		(227,646)
Accumulated Deficit		(222,644,402)		(217,775,903)
Total Stockholders' Equity		33,662,609		38,407,626
			-	
Total Liabilities and Stockholders' Equity	\$	74,133,999	\$	45,803,522

See accompanying notes to unaudited consolidated financial statements

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# AVANT IMMUNOTHERAPEUTICS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended					
	 March 31, 2005		March 31, 2004			
REVENUE:						
Product Development and Licensing Agreements	\$ 71,457	\$	2,124,419			
Government Contracts and Grants	866,087		879,908			
Product Royalties	33,008		26,370			

Total Revenue	970,552		3,030,697
OPERATING EXPENSE:			
Research and Development	4,030,618		3,453,200
General and Administrative			
	1,710,784		1,292,135
Amortization of Acquired Intangible Assets	248,778		248,778
Total Operating Expense	5,990,180		4,994,113
		-	
Operating Loss	(5,019,628)		(1,963,416)
Investment and Other Income, Net	151,129		54,002
Net Loss	\$ (4,868,499)	\$	(1,909,414)
Basic and Diluted Net Loss Per Common Share	\$ (0.07)	\$	(0.03)
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Weighted Average Common Shares Outstanding	74,131,999		69,169,571

See accompanying notes to unaudited consolidated financial statements

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# AVANT IMMUNOTHERAPEUTICS, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

		Three Months Ended			
	_	March 31, 2005			
Cash Flows from Operating Activities:					
Net Loss	\$	(4,868,499)	\$	(1,909,414)	
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		( , , ,		( )= ,	
Depreciation and Amortization		342,351		352,661	
Amortization of Deferred Compensation		121,000		69,000	
Changes in Operating Assets and Liabilities:		,		,	
Accounts Receivable		1,313,899		(179,762)	
Prepaid and Other Current Assets		(100,829)		(44,522)	
Accounts Payable and Accrued Expenses		(878,909)		630,289	
Deferred Revenue		25,795		(1,074,419)	
Deterred the tende		20,700		(1,07 1,110)	
Net Cash Used in Operating Activities		(4,045,192)		(2,156,167)	
11ct Cush Oscu in Operating Activities	_	(4,045,152)		(2,130,107)	
Cash Flows from Investing Activities:					
Other Non-Current Assets		1,000		3/4	
Acquisition of Property and Equipment		(359,717)		(244,288)	
Net Cash Used in Investing Activities		(358,717)		(244,288)	
Cash Flows from Financing Activities:					
Proceeds from Stock Issuance		2,055		23,090,725	
Proceeds from Exercise of Stock Options and Warrants		427		220,137	
Payment of Long-Term Liabilities		(30,947)		3/4	
Net Cash Provided by (Used in) Financing Activities		(28,465)		23,310,862	
		·			
Net Increase (Decrease) in Cash and Cash Equivalents		(4,432,374)		20,910,407	
Cash and Cash Equivalents at Beginning of Period		31,741,494		18,251,044	
Cash and Cash Equivalents at End of Period	\$	27,309,120	\$	39,161,451	
Supplemental Disclosure of Cash Flow Information					
Cash paid for interest	\$	31,108		3/4	
See Note 8.					

See accompanying notes to unaudited consolidated financial statements

## AVANT IMMUNOTHERAPEUTICS, INC. Notes to Unaudited Consolidated Financial Statements March 31, 2005

#### (1) Nature of Business

AVANT Immunotherapeutics, Inc. is engaged in the discovery, development and commercialization of products that harness the human immune system to prevent and treat disease. The Company is developing a broad portfolio of vaccines and therapeutics against cardiovascular, viral and bacterial diseases. These include a treatment to reduce complement-mediated tissue damage associated with cardiac by-pass surgery, single-dose oral vaccines aimed at protecting travelers and people in endemic regions from infectious diseases and a proprietary vaccine candidate for cholesterol management. In addition, the Company is developing the VitriLifeÒ preservation technology for use in AVANT's oral vaccines and certain other non-injectable applications. 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. ("Megan"). All intercompany transactions have been eliminated.

#### (2) Interim Financial Statements

The accompanying unaudited consolidated financial statements for the three months ended March 31, 2005 and 2004 include the consolidated accounts of AVANT, and have been prepared in accordance with instructions to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, the information contained herein reflects all adjustments, consisting solely of normal recurring adjustments, that are necessary to present fairly the Company's financial position at March 31, 2005, results of operations for the three-month periods ended March 31, 2005 and 2004, and cash flows for the three-month periods ended March 31, 2005 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, 2004, are adequate to make the information presented not misleading.

#### (3) Recent Accounting Pronouncement

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), which replaces SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123") and supercedes APB Opinion No. 25, "Accounting for Stock Issued to Employees". SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values, beginning with the first annual period after June 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under SFAS 123, no longer will be an alternative to financial statement recognition. AVANT is required to adopt SFAS 123R in our first quarter of 2006, beginning January 1, 2006. Under SFAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive options, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive

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methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. AVANT is evaluating the requirements of SFAS 123R and the adoption of SFAS 123R which may have a material impact on its consolidated results of operations and earnings per share. The Company has not yet determined the method of adoption or the effect of adopting SFAS 123R, and has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123.

#### (4) Stock-Based Compensation

As permitted by Statement of Financial Accounting Standards ("SFAS") No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of SFAS 123", AVANT has accounted for its stock-based compensation awards using the intrinsic method and disclosed the effect on the net loss per share as if the fair value method had been used. AVANT periodically grants stock options for a fixed number of shares to employees and directors with an exercise price equal to the fair market value of the shares at the date of grant. The Company accounts for employee and director stock options under the recognition and measurement principles of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees", and related interpretations.

In November 2004 and September 2003, the Company awarded Restricted Stock Units to Dr. Una S. Ryan, Ph.D., the Company's President and CEO, and recorded non-cash deferred compensation amounting to \$832,000 and \$1,104,000, respectively. The value of the Restricted Stock Units is being amortized over their vesting period, or four years, and being recorded as compensation expense. The Company has recognized \$121,000 and \$69,000 as stock based compensation expense in the statement of operations during the three-month periods ended March 31, 2005 and 2004, respectively.

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

		larch 31,		
		2005		2004
Net Loss:				
As reported	\$	4,868,499	\$	1,909,414
Less: Stock-based employee compensation expense as reported		(121,000)		(69,000)
Add: Total stock-based employee compensation expense determined under fair value based method for all		258,389		171,300

awards		
Pro forma	\$ 5,005,888	\$ 1,807,114
Basic and Diluted Net Loss Per Share:		
As reported	\$ 0.07	\$ 0.03
Pro forma	0.07	0.03

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,
	2005	2004
Expected stock price volatility	85%	109%
Expected option term	5 Years	5 Years
Risk-free interest rate	3.6 - 4.3%	2.7 - 3.5%
Expected dividend yield	None	None

Because additional stock-based compensation 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.

## (5) Trade and Other Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company has not historically experienced credit losses from its trade accounts receivable and therefore has not established an allowance for doubtful accounts.

Accounts receivable consists of the following:

	_	March 31, 2005	 December 31, 2004
Trade Receivables	\$	888,877	\$ 2,205,176
Other Receivables		27,574	25,174
	\$	916,451	\$ 2,230,350

Other receivables at March 31, 2005 and December 31, 2004 primarily represent interest receivable from a bank.

## (6) Property and Equipment

Property and equipment includes the following:

	March 31, 2005			December 31, 2004
Laboratory Equipment	\$	2,463,233	\$	2,390,458
Office Furniture and Equipment		1,755,724		1,665,401
Leasehold Improvements		1,704,590		1,704,590
Construction in Progress		3,670,199		3,473,580
Property and Equipment, Total		9,593,746		9,234,029
Less Accumulated Depreciation and Amortization		(5,163,310)		(5,069,737)
	\$	4,430,436	\$	4,164,292

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## (7) <u>Intangible and Other Assets</u>

Intangible and other assets include the following:

	March 31, 2005											
	Estimated Lives	]	Gross Intangible Assets		ccumulated mortization		Net Intangible Assets		Gross Intangible Assets	 ccumulated mortization	I	Net ntangible Assets
Intangible Assets:												
Collaborative Relationships	5 years	\$	1,090,000	\$	(1,090,000)	\$	_	\$		\$ (1,090,000)	\$	_
Core Technology	10 years		3,786,900		(1,224,332)		2,562,568		3,786,900	(1,129,658)		2,657,242
Developed Technology	7 years		3,263,100		(2,017,600)		1,245,500		3,263,100	(1,901,200)		1,361,900
Strategic Partner Agreement	17 years		2,563,900		(653,542)		1,910,358		2,563,900	(615,838)		1,948,062
Total Intangible Assets			10,703,900		(4,985,474)		5,718,426		10,703,900	(4,736,696)		5,967,204
Other Non Current Assets			94,981		3/4		94,981		95,981	3/4		95,981
		\$	10,798,881	\$	(4,985,474)	\$	5,813,407	\$	10,799,881	\$ (4,736,696)	\$	6,063,185

All of the Company's intangible assets are amortized over their estimated useful lives. Total amortization expense for intangible assets was \$248,778 for the three-month periods ended March 31, 2005 and 2004, respectively.

The estimated future amortization expense of intangible assets as of March 31, 2005 for the remainder of fiscal year 2005 and the five succeeding years is as follows:

Year ending December 31,	Amortiza	Estimated Amortization Expense					
2005 (remaining nine months)	\$	746,334					
2006		995,112					
2007		960,212					
2008		529,512					
2009		529,512					
2010		514,622					

#### (8) Loss Per Share

The Company computes and reports earnings per share in accordance with the provisions of SFAS No. 128, "Earnings Per Share". The computations of basic and diluted loss per common share are based upon the weighted average number of common shares outstanding and potentially dilutive securities. Potentially dilutive securities include stock options, warrants and restricted stock units. Options and warrants to purchase 3,615,528 and 3,517,728 shares of common stock and restricted stock units totaling 800,000 and 400,000 shares were not included in the computations of weighted average common shares for the periods ended March 31, 2005 and 2004, respectively, because inclusion of such shares would have an anti-dilutive effect on net loss per share.

#### (9) Product Development and Licensing Agreements

AVANT's revenue from product development and licensing agreements was received pursuant to contracts with different organizations. Total revenue recognized by the Company in connection with these contracts for the three-month periods ended March 31, 2005 and 2004 were \$71,457 and \$2,124,419, respectively. A summary of these contracts follows:

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#### (A) GlaxoSmithKline plc ("Glaxo")

During 1997, AVANT entered into an agreement with Glaxo to collaborate on the development and commercialization of the Company's oral rotavirus vaccine and Glaxo assumed responsibility for all subsequent clinical trials and all other development activities. Glaxo initiated global Phase III clinical trials of Rotarix® in the third quarter of 2003 and AVANT recognized a \$1 million milestone as revenue. Glaxo filed for market approval with the European regulatory authorities in late 2004, triggering a \$2 million milestone fee payable to AVANT, 50% of which is creditable against future royalties. The amount was recorded as revenue in 2004 as AVANT has no obligation to incur any research and development costs in connection with this agreement. AVANT is obligated to maintain a license with an academic institution with respect to this agreement and incurred licensing fees of \$200,000 in both 2004 and 2003. In addition, the Company recorded \$300,000 of expense in the fourth quarter of 2004 for amounts which will be payable to this institution in connection with the aforementioned 2004 milestone payment. The recording of this 2004 expense accrual satisfies AVANT's minimum license fee obligations for 2005. All licensing fees are included in research and development expense. The term of this agreement is through the expiration of the last of the relevant patents covered by the agreement, although Glaxo may terminate the agreement upon 90 days prior written notice. Glaxo has agreed to make further payments, which could total up to \$5.5 million, upon the achievement of specified milestones. In addition, AVANT will be entitled to royalties based on net sales of Rotarix®.

## (B) Pfizer Inc ("Pfizer")

In connection with the Company's acquisition of Megan, it entered into a licensing agreement with Pfizer's Animal Health Division whereby Pfizer has licensed Megan's technology for the development of animal health and food safety vaccines. Under the agreement, AVANT may receive additional milestone payments of up to \$3 million based upon attainment of specified milestones. AVANT may receive royalty payments on eventual product sales. The term of this agreement is through the expiration of the last of the patents covered by the agreement. AVANT has no obligation to incur any research and development costs in connection with this agreement.

#### (C) DynPort Vaccine Company LLC ("DVC")

In October 2001, the Company granted DVC a license for exclusive rights to use certain components of its anthrax vaccine technology. Under the agreement, AVANT is entitled to annual \$50,000 license maintenance payments, with respect to which AVANT has received \$200,000 in the aggregate, including \$50,000 received in the first quarter of 2005, and milestone payments of up to \$700,000 in the aggregate, \$100,000 of which AVANT recognized as revenue in 2002. The annual license fee is recognized as revenue on a straight line basis over the year. AVANT is also entitled to specified royalties on eventual product sales. The term of this agreement is through the expiration of the last of the patents covered by the agreement, although DVC may terminate the agreement upon 90 days prior written notice. AVANT has no obligation to incur any research and development costs in connection with this agreement.

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

In January 2003, AVANT was awarded a subcontract by DVC in the amount of \$2.5 million to develop for the U.S. Department of Defense an oral combination vaccine against anthrax and plague using AVANT's proprietary vaccine technologies. As of March 31, 2005, AVANT has received a number of additional subcontract modifications from DVC to support preclinical animal testing of vaccine constructs and the start of human clinical testing of a plague vaccine candidate being developed by AVANT for use in the oral combination vaccine.

Total contract funding from DVC now totals approximately \$7 million. The Defense Appropriations Bill for Fiscal Year 2005 passed by Congress in July 2004 committed an additional \$2.8 million in funding to this vaccine program. Aggregate funding commitments for this program now approximate \$10 million to cover vaccine development. 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. For the three months ended March 31, 2005 and 2004, AVANT recognized \$835,557 and \$846,166, respectively, in government contract revenue from DVC. Through March 31, 2005, AVANT had received approximately \$5.9 million in payments under the subcontract agreements. These agreements expire in 2006, although they may be terminated by DVC at any time upon 30 days notice.

#### (D) AdProTech, Ltd ("AdProTech")

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

#### (10) <u>Long-Term Liabilities</u>

In December 2003, AVANT entered into a Lease Agreement, a Secured Promissory Note: Equipment Loan and a Security Agreement with the Massachusetts Development Finance Agency ("MassDevelopment"), an economic development entity for the Commonwealth of Massachusetts, for AVANT to occupy and build-out a manufacturing facility in Fall River, Massachusetts.

## (A) Loan Payable

Under the Lease Agreement, AVANT received a Specialized Tenant Improvement Allowance of \$1,227,800 to finance the build-out of the Fall River facility. Principal and interest payments of the aggregate disbursement increments are due monthly using an amortization period of 15 years and an interest rate of 5.5% per annum.

At March 31, 2005, AVANT has recorded leasehold improvement assets of \$1,227,800 as construction in progress and currently has a loan payable of \$1,207,337 to MassDevelopment, of which \$59,800 is classified as current and \$1,147,537 as long-term. AVANT has determined that the lease term is shorter than the estimated economic life of the assets and as of this date there is no decision to renew the lease for an additional period. AVANT will reevaluate the amortization period of the leasehold improvement assets if circumstances change. AVANT will amortize the leasehold improvement assets over the remaining lease term beginning when validation of the Fall River facility is completed and it is operational. Based on current market interest rates available to AVANT for long-term liabilities with similar terms and maturities, the fair value of the loan payable is approximately \$895,000 at March 31, 2005.

#### (B) Note Payable

Under the Secured Promissory Note: Equipment Loan, AVANT received \$903,657 from MassDevelopment to finance the purchases of equipment to be placed in the Fall River facility. The Loan has a term of 84 months at an interest rate of 5.5% per annum. The Loan is collateralized by all of the equipment purchased with the principal amount.

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At March 31, 2005, AVANT has recorded manufacturing and laboratory equipment assets of \$903,657 as construction in progress and currently has a note payable of \$893,173 to MassDevelopment, of which \$126,709 is classified as current and \$766,464 as long-term. AVANT will depreciate the manufacturing and laboratory equipment assets over the estimated economic lives of the assets beginning when validation of the Fall River facility is completed and ready for its intended use which is expected to be by third quarter 2005. Based on current market interest rates available to AVANT for long-term liabilities with similar terms and maturities, the fair value of the note payable is approximately \$797,000 at March 31, 2005.

## (11) <u>Commitments and Contingencies</u>

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

In August 2004, AVANT entered into a Design/Build Contract with a design/builder for the build-out of the Fall River facility. The final contract amount including work change orders made during the construction period totaled \$2,256,000. As of March 31, 2005, AVANT had made payments and accrued costs totaling \$2,088,100 under the Contract.

#### (B) Purchase Commitments for Contract Manufacturing

In April 2000, AVANT entered into a Services Agreement (the "Lonza Agreement") with Lonza Biologics plc ("Lonza") for process development and manufacture of its product candidate TP10. During the three-month period ended March 31, 2005 and the year ended December 31, 2004, AVANT entered into a number of amendments to the Lonza Agreement for specific process development and scale-up work totaling approximately \$78,500 and \$4,938,300, respectively. Remaining aggregate commitments as of March 31, 2005 under the Lonza Agreement total \$3,298,900. The Company has incurred \$733,363 and \$6,008,976, respectively, of expense related to the Lonza Agreement in the three-month period ended March 31, 2005 and from inception through March 31, 2005, of which \$987,531 remained accrued at March 31, 2005.

In May 2004, AVANT signed an Amendment to the Lonza Agreement for the cGMP production of TP10 at commercial scale scheduled for the first quarter of 2005. Due to development delays, AVANT and Lonza have mutually agreed to reschedule the production run to the first quarter of 2006. Under the terms of the Lonza Agreement, if AVANT voluntarily terminates the Amendment within four months of the expected start date of the cGMP production run, AVANT is obligated to pay a termination fee of approximately \$720,000. AVANT currently has no plans to terminate this production run.

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 plaque or any other microbes used as bioweapons and other disease causing agents; (3) the ability to successfully complete development and commercialization of TP10, CETi-1, CholeraGarde® (Peru-15), Ty800 and other products; (4) the cost, timing, scope and results of ongoing safety and efficacy trials of TP10, CETi-1, CholeraGarde® (Peru-15), Ty800 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, CETi-1, CholeraGarde® (Peru-15), Ty800 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, Megan®Egg and other future products; (8) the process of obtaining regulatory approval for the sale of RotarixÒ in major commercial markets, as well as the timing and success of worldwide commercialization of RotarixÒ by our partner, GlaxoSmithKline; (9) changes in existing and potential relationships with corporate collaborators; (10) the availability, cost, delivery and quality of clinical and commercial grade materials supplied by contract manufacturers; (11) the timing, cost and uncertainty of obtaining regulatory approvals to use TP10, CETi-1, CholeraGarde® (Peru-15) and Ty800, among other purposes, for adults undergoing cardiac surgery, to raise serum HDL cholesterol levels and to protect travelers and people in endemic regions from diarrhea causing diseases, respectively; (12) the ability to obtain substantial additional funding; (13) the ability to develop and commercialize products before competitors; (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. 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 principal activity since our inception has been research and product development conducted on its own behalf, as well as through joint development programs with several pharmaceutical companies and other collaborators. AVANT was incorporated in the State of Delaware in December 1983.

## CRITICAL ACCOUNTING POLICIES

The Company's critical accounting policies are set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 to our 2004 Form 10-K. There have been no changes to these policies since December 31, 2004. Readers are encouraged to review these critical accounting policies in conjunction with the review of this Form 10-Q.

## **OVERVIEW**

AVANT's focus is unlocking the power of the immune system to prevent and treat disease. The Company has assembled a broad portfolio of technologies and intellectual property that give it a strong competitive position in vaccines and immunotherapeutics. These include an oral human rotavirus vaccine, which gained its first marketing approval in Mexico in July 2004. Six of AVANT's products are in clinical development. The Company's goal is to become a leading developer of innovative vaccines and immunotherapeutics that address health care needs on a global basis.

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

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

## ACQUISITIONS

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

Megan Health, Inc.: On December 1, 2000, AVANT acquired all of the outstanding capital stock of Megan Health, Inc. ("Megan"), a company engaged in the discovery and development of human and animal vaccines using patented gene modification technologies. In connection with the acquisition, AVANT recorded a charge of \$9,012,300 for acquired in-process research and development ("IPR&D"), which represented purchased in-process technology which had not yet reached technological feasibility and had no alternative future use. As of March 31, 2005, none of the acquired research and development projects had reached technological feasibility.

Virus Research Institute, Inc.: On August 21, 1998, AVANT acquired Virus Research Institute, Inc. ("VRI"), a company engaged in the discovery and development of systems for the delivery of vaccines and immunotherapeutics, and novel vaccines for adults and children. In connection with the acquisition, AVANT recorded a charge of \$44,630,000 for acquired IPR&D, which represented purchased in-process technology which had not yet reached technological feasibility and had no alternative future use. As of March 31, 2005, only RotarixÒ of the acquired research and development projects had reached technological feasibility as it received marketing approval in Mexico.

#### RESEARCH AND DEVELOPMENT ACTIVITIES

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

During the past five years through the end of 2004, AVANT incurred an aggregate of \$71 million in research and development costs. During the three months ended March 31, 2005, AVANT incurred an aggregate of \$4.0 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 two years ended December 31, 2004 and 2003 and the three-month

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periods ended March 31, 2005 and 2004. 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.

	Three Months Ended March 31,				Years Ended December 31,				
	2005		2004		2004		2003		
Bacterial Vaccines:									
CholeraGardeÒ	\$ 92,100	\$	26,500	\$	123,100	\$	695,800		
Ty800	130,500		168,900		688,300		186,300		
Other	116,600		30,900		332,500		137,500		
BioDefense Vaccines:	565,800		1,066,400		3,082,800		3,524,500		
Cholesterol Management Vaccine:									
CETi-1	155,000		155,100		816,900		3,404,000		
Complement Inhibitors:									
TP10/TP20	2,686,400		1,847,700		7,706,300		1,648,700		
Food Safety & Animal Health Vaccines:	700		6,900		12,600		49,400		
Viral Vaccines:									
RotarixÒ vaccine	3⁄4		50,000		500,000		200,000		
TheraporeÒ/HIV	1,500		54,300		184,900		72,400		
Other Programs:	282,000		46,500		426,400		102,700		
			_		_				
Total R&D Expense	\$ 4,030,600	\$	3,453,200	\$	13,873,800	\$	10,021,300		

#### PROGRAM DEVELOPMENTS

Rotavirus Vaccine: Rotavirus is a major cause of diarrhea and vomiting in infants and children. In 1997, AVANT licensed its oral rotavirus vaccine to Glaxo. All of the ongoing development for this program is being conducted and funded by Glaxo. During the period January 1, 2000 through December 31, 2004, AVANT incurred approximately \$1.6 million in licensing fees and \$79,000 in research and development costs. During the three months ended March 31, 2005, AVANT did not incur any licensing fees associated with the rotavirus program. Glaxo initiated global Phase III clinical trials of Rotarix®, its two-dose oral rotavirus vaccine, in the third quarter of 2003 and AVANT recognized a \$1.0 million milestone. Glaxo gained approval for RotarixÒ in Mexico in July 2004, which represents the first in an expected series of worldwide approvals and commercial launches for the product. Glaxo has already filed for market approval in more than 30 countries worldwide and plans to launch in additional Latin American and Asia Pacific countries during the course of 2005. Additionally, Glaxo filed for market approval with the European regulatory authorities in late 2004, which triggered a \$2 million milestone payment to AVANT. Assuming product development and commercialization continues satisfactorily, AVANT may receive additional milestone payments totaling \$5.5 million upon the achievement of specified milestones. In addition, AVANT will be entitled to royalties based on worldwide net sales of Rotarix®.

Complement Inhibitors: In February 2002, AVANT announced that TP10 had not achieved a significant reduction in the primary endpoint of a Phase II adult cardiac surgery trial conducted in 564 patients. However, further analysis of the study data demonstrated an important treatment benefit in male patients participating in the trial directly related to mortality, which was impressive, however, with no significant treatment benefit observed in female patients. In February 2004, AVANT started a Phase IIb double-blind, placebo-controlled trial of TP10 in approximately 300 women undergoing cardiopulmonary by-pass surgery. The trial will examine the effect of TP10 versus placebo at approximately 30 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

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design of a subsequent registration-directed trial. AVANT plans to seek a corporate partner to complete development and to commercialize TP10 prior to starting a Phase III clinical trial.

During the period January 1, 2000 through December 31, 2004, AVANT incurred approximately \$30.5 million in research, development, contract manufacturing and clinical costs. During the three months ended March 31, 2005, the Company incurred approximately \$2.7 million in research, development, contract manufacturing and clinical costs associated with its complement program.

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

Development of a safe, effective cholera vaccine is the first step in establishing AVANT's single-dose, oral bacterial vaccine franchise. During 2002, AVANT completed a Phase II dose-ranging study with CholeraGarde® which confirmed the safety and activity of this vaccine and supported the start of Phase II trials in December 2002 with the International Vaccine Institute ("IVI") in Bangladesh where cholera is endemic. IVI is assessing the safety and immunogenicity of the vaccine in adults, toddlers and infants as young as nine months of age. IVI has completed testing in all study groups and results are expected to be announced in mid-2005. Published results have shown the vaccine to be well tolerated and immunogenic against the cholera organism in the adult portion of this trial.

During the period January 1, 2000 through December 31, 2004, AVANT incurred approximately \$9.3 million in research, development and clinical costs on its CholeraGarde® program. During the three months ended March 31, 2005, AVANT incurred approximately \$92,100 in research, development and clinical costs on its CholeraGarde® program.

AVANT is also developing an oral typhoid fever vaccine, Ty800, for global health needs. The National Institute of Allergy and Infectious Disease (NIAID) of the National Institutes of Health (NIH) and AVANT have agreed for the NIAID to conduct a Phase I/II in-patient dose-ranging clinical trial aimed at demonstrating the safety and immunogenicity of the Ty800 vaccine. NIAID has funded the production of Ty800 vaccine for clinical testing and expects to initiate the Phase I/II trial at a NIH-funded clinical site in 2005. 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, 2004, AVANT incurred approximately \$5 million in research, development, contract manufacturing and clinical costs on its Ty800 program. During the three months ended March 31, 2005, AVANT incurred approximately \$130,500 in research, development and clinical costs on its Ty800 program.

Finally, AVANT is developing three additional bacterial vaccines against enterotoxigenic *E. coli* ("ETEC"), *Shigella* and *Campylobacter*—all important causes of serious diarrheal diseases worldwide. These three programs are in pre-clinical development. In 2005, AVANT expects to allocate resources to further the development of a two-vaccine combination product containing ETEC and Shigella or Campylobacter addressed to the travelers' market.

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

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

Further, in January 2003, AVANT was awarded a subcontract by DVC in the amount of \$2.5 million to develop for the U.S. Department of Defense an oral combination vaccine against anthrax and plague using AVANT's proprietary vaccine technologies. As of March 31, 2005, AVANT has received a number of additional subcontract modifications from DVC to support preclinical animal testing of vaccine constructs and the start of human clinical testing of a plague vaccine candidate being developed by AVANT for use in the oral combination vaccine. Total contract funding from DVC now totals approximately \$7 million. The Defense Appropriations Bill for Fiscal Year 2005 passed by Congress in July 2004 committed an additional \$2.8 million in funding to this vaccine. program. Aggregate funding commitments for this program now approximate \$10 million to cover vaccine development. 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. For the three months ended March 31, 2005 and 2004, AVANT recognized \$835,557 and \$846,166, respectively, in government contract revenue from DVC. Through March 31, 2005, AVANT had received approximately \$5.9 million in payments under the subcontract agreements. These agreements expire in 2006, although they may be terminated by DVC at any time upon 30 days notice.

During the period January 1, 2000 through December 31, 2004, AVANT incurred approximately \$6.8 million in research and development costs on its biodefense vaccine program. During the three months ended March 31, 2005, AVANT incurred approximately \$565,800 in research and development costs on its biodefense vaccine program.

Food Safety and Animal Health Vaccines: AVANT has partnered with Pfizer, who will apply AVANT's vaccine technologies to animal health and human food safety markets. The Pfizer research program achieved an important milestone in late 2002, which resulted in a payment of \$500,000 to AVANT. During the period January 1, 2000 through December 31, 2004, AVANT incurred approximately \$1.6 million in research and development costs on its food safety and animal health vaccines program. During the three months ended March 31, 2005, AVANT incurred approximately \$1,500 in research and development costs on its food safety and animal health vaccines program.

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

In October 2003, AVANT completed the CETi-1 vaccine Phase II efficacy study in approximately 200 patients with low levels of HDL cholesterol. The results of the study demonstrated proof-of-concept in humans confirming that blocking cholesterol transfer could raise HDL levels. In addition, the CETi-1

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formulated vaccine. During the period January 1, 2000 through December 31, 2004, AVANT incurred approximately \$11.7 million in research, development and clinical costs associated with the CETi program. During the three months ended March 31, 2005, AVANT incurred approximately \$155,000 in research, development and clinical costs associated with the CETi program. AVANT plans to seek a corporate partner to complete development and to commercialize the CETi vaccine.

#### 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 DVC for exclusive rights to use certain components of AVANT's vaccine technology. Financial terms of the agreement with DVC include license fees, milestone payments and royalties.

*AdProTech:* In March 2004, AVANT granted a license to AdProTech for non-exclusive rights to use certain components of its intellectual property surrounding complement inhibition. Financial terms of the agreement with AdProTech include license fees, milestone payments and royalties. AdProTech was acquired by Inflazyme Pharmaceuticals Ltd. in April 2004 which assumed the license.

#### RESULTS OF OPERATIONS

Three-Month Period Ended March 31, 2005 as Compared with the Three-Month Period Ended March 31, 2004

AVANT reported consolidated net loss of \$4,868,499, or \$.07 per share, for the first quarter ended March 31, 2005, compared with a net loss of \$1,909,414, or \$.03 per share, for the first quarter ended March 31, 2004. The weighted average common shares outstanding used to calculate net loss per common share was 74,231,999 in 2005 and 69,169,571 in 2004.

Revenue: Total revenue decreased \$2,060,145 to \$970,552 for the first quarter of 2005 compared to \$3,030,697 for the first quarter of 2004.

Product development and licensing revenue decreased \$2,052,962, or 97%, to \$71,457 in 2005 from \$2,124,419 in 2004. Product development and licensing revenue in 2004 consisted primarily of a one-time recognition of \$1 million in revenue from DVC for rPA clinical materials and a one-time license fee of \$1 million from AdProTech as well as the amortization of nonrefundable license fees from Pfizer which was fully amortized by November 2004.

AVANT has received a number of subcontracts from its partner, DVC, to develop anthrax and plague vaccines for the U.S. Department of Defense. AVANT will be reimbursed by DVC on a time and materials basis for vaccine development research work performed by AVANT. Under these agreements and several SBIR grants, AVANT recognized \$866,087 and \$879,908 in government contract and grant revenue during the first quarters of 2005 and 2004, respectively, for work performed. AVANT expects the amount of research work to be performed for DVC during the remainder of 2005 to increase when compared to the amount of research work performed during the comparable period in 2004.

Marketing and distribution of the Megan poultry product line is performed by AVANT's partner, Lohmann Animal Health International ("LAHI"), and AVANT receives a royalty percentage of all Megan®Vac 1 and Megan®Egg product sales. Royalty payments received during the first quarter of 2005 and 2004 totaled \$33,008 and \$26,370, respectively. In early March 2005, the USDA placed a stop sale order on MeganÒVac 1 and MeganÒEgg, for LAHI's failure to update the Outline of Production as LAHI

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improved the fermentation process. LAHI is in the process of updating the Outline of Production. If the USDA requires LAHI to perform efficacy trials for both vaccines, MeganÒVac 1 and MeganÒEgg would not be marketed for several months, which would cause AVANT to lose potential royalty revenues.

*Operating Expense:* Total operating expense increased \$996,067, or 19.9%, to \$5,990,180 for the first quarter of 2005 compared to \$4,994,113 for the first quarter of 2004.

Research and development expense increased \$577,418, or 16.7%, to \$4,030,618 in 2005 from \$3,453,200 in 2004. The increase in 2005 compared to 2004 is primarily due to increases in contract manufacturing costs of \$307,112 incurred for process development and scale-up work associated with the TP10 program and increased personnel, operating and facility-related costs of \$413,585 associated with the start-up operations of the Fall River facility. These increases were offset in part by declines in clinical trials costs of \$255,732, license fees of \$56,250, and research and development consultancy costs of \$42,129. AVANT expects research and development expense to increase substantially in 2005 as the TP10 Phase II female clinical trial reaches full enrollment, as AVANT's contract manufacturer completes process development and scale-up work and as the Fall River facility is brought to full operational status.

General and administrative expense increased \$418,649, or 32.4%, to \$1,710,784 in 2005 compared to \$1,292,135 in 2004 and is primarily attributed to increases in personnel and related costs of \$149,447, legal and other professional fees of \$171,214, and consultancy costs of \$106,699 related to project management and Sarbanes-Oxley compliance. AVANT expects general and administrative expense to continue at this level for the balance of 2005.

Amortization expense of acquired intangible assets was \$248,778 in 2005 and 2004.

*Investment and Other Income, Net:* Interest and other income increased \$97,127 to \$151,129 for the first quarter of 2005 compared to \$54,002 for the first quarter of 2004. The increase is primarily due to higher interest rates during the first quarter of 2005 compared to the first quarter of 2004. During the first quarters of 2005 and 2004, the average month-end cash balances were \$29,465,071 and \$34,128,874, respectively. The effective interest rates during the first quarters of 2005 and 2004 were 2.33% and 0.96%, respectively.

## LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2005, AVANT's principal sources of liquidity consisted of cash and cash equivalents of \$27,309,120. AVANT's cash and cash equivalents are highly liquid investments with a maturity of three months or less at the date of purchase and consist of time deposits and investments in money market mutual funds with commercial banks and financial institutions, short-term commercial paper, and U.S. Government and other investment grade debt securities. Also, the Company maintains cash balances with financial institutions in excess of insured limits. AVANT does not anticipate any losses with respect to such cash balances.

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

Net cash used in operating activities increased to \$4,045,192 for the first quarter of 2005 compared to \$2,156,167 for the first quarter of 2004. The increase is primarily attributed to an increase in net loss

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incurred in 2005 compared to 2004 and a decrease in accounts payable and accrued expenses due to timing of payments, offset partly by the decrease in accounts receivable, which related primarily to the \$2,000,000 Glaxo milestone fee received in January 2005. AVANT expects that cash used in operations will continue to increase in 2005 as the Company continues to develop its products in clinical trials, contacts for the manufacture of clinical materials, brings its Fall River facility to full operational status and advances new products into preclinical development. The expected increase in cash used would be partially offset by anticipated payments made under the Company's government contracts and grants and anticipated product royalty payments.

Cash used in investing activities increased to \$358,717 for the first quarter of 2005 compared to \$244,288 for the first quarter of 2004. The increase is due to increased investment in property and equipment in 2005 primarily for the Fall River facility compared to 2004. AVANT expects it will continue to use cash in its investing activities as the Company expands its infrastructure and completes the validation of the Fall River facility and brings it to operational status.

Net cash used in financing activities was \$28,465 for the first quarter of 2005 compared to net cash provided by financing activities \$23,310,862 for the first quarter of 2004. The decrease in financing activities between years is due primarily to the completion of a direct equity placement in the first quarter of 2004.

#### AGGREGATE CONTRACTUAL OBLIGATIONS

The following table summarizes AVANT's contractual obligations at March 31, 2005 and the effect such obligations and commercial commitments are expected to have on its liquidity and cash flow in future years. These obligations, commitments and supporting arrangements represent payments based on current operating forecasts, which are subject to change:

Total		2005		2006-2007		2008-2009		Thereafter	
\$	6,428,900	\$	1,849,600	\$	4,041,100	\$	538,200	\$	_
	2,785,600		244,100		950,100		610,500		980,900
	573,800		63,800		255,000		170,000		85,000
	167,900		167,900		_		_		_
\$	9,956,200	\$	2,325,400	\$	5,246,200	\$	1,318,700	\$	1,065,900
\$	2,818,600	\$	2,818,600	\$	_	\$	_	\$	_
	3,298,900		1,498,900		1,800,000				_
\$	6,117,500	\$	4,317,500	\$	1,800,000	\$	_	\$	_
	\$	\$ 6,428,900 2,785,600 573,800 167,900 \$ 9,956,200 \$ 2,818,600 3,298,900	\$ 6,428,900 \$ 2,785,600 573,800 167,900 \$ 9,956,200 \$ \$ \$ 2,818,600 \$ 3,298,900	\$ 6,428,900 \$ 1,849,600 2,785,600 244,100 573,800 63,800 167,900 167,900 \$ 9,956,200 \$ 2,325,400 \$ 2,818,600 \$ 2,818,600 3,298,900 1,498,900	\$ 6,428,900 \$ 1,849,600 \$ 2,785,600 244,100 573,800 63,800 167,900 \$ 9,956,200 \$ 2,325,400 \$ \$ 2,818,600 \$ 3,298,900 1,498,900	\$ 6,428,900 \$ 1,849,600 \$ 4,041,100 2,785,600 244,100 950,100 573,800 63,800 255,000 167,900 167,900 —— \$ 9,956,200 \$ 2,325,400 \$ 5,246,200 \$ 2,818,600 \$ 2,818,600 \$ — 3,298,900 1,498,900 1,800,000	\$ 6,428,900 \$ 1,849,600 \$ 4,041,100 \$ 2,785,600 244,100 950,100 573,800 63,800 255,000 167,900 —   \$ 9,956,200 \$ 2,325,400 \$ 5,246,200 \$ \$ \$ 2,818,600 \$ — \$ 3,298,900 1,498,900 1,800,000	\$ 6,428,900 \$ 1,849,600 \$ 4,041,100 \$ 538,200 2,785,600 244,100 950,100 610,500 573,800 63,800 255,000 170,000 167,900 — — — — — \$ 9,956,200 \$ 2,325,400 \$ 5,246,200 \$ 1,318,700 \$ \$ 2,818,600 \$ 2,818,600 \$ — \$ — 3,298,900 1,498,900 1,800,000 —	\$ 6,428,900 \$ 1,849,600 \$ 4,041,100 \$ 538,200 \$ 2,785,600 244,100 950,100 610,500 573,800 63,800 255,000 170,000 167,900 — — — — \$ 9,956,200 \$ 2,325,400 \$ 5,246,200 \$ 1,318,700 \$ \$ \$ 2,818,600 \$ 2,818,600 \$ — \$ — \$ 3,298,900 1,498,900 1,800,000 —

<sup>\*</sup> includes interest obligations

## Item 3. Quantitative and Qualitative Disclosures about Market Risk

AVANT owns financial instruments that are sensitive to market risk as part of its investment portfolio. The Company investment portfolio is used to preserve its capital until it is used to fund operations, including its research and development activities. None of these market-risk sensitive instruments are held for trading purposes. AVANT invests its 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. The Company's investment portfolio includes only marketable securities with active secondary or resale markets to help insure liquidity. AVANT has implemented investment policies regarding the amount and credit ratings of investments. Because of the short-term nature of these investments, AVANT does not

believe it has material exposure due to market risk. The impact to AVANT's financial position and results of operations from likely changes in interest rates is not material.

AVANT does 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, 2005 due to the short-term maturities of these instruments.

#### **Item 4. Controls and Procedures**

Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as of March 31, 2005, 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 March 31, 2005, 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 significant change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### PART II — OTHER INFORMATION

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

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 (Item 12) was filed on March 2, 2005 regarding a press release announcing that AVANT had reported its financial results for the fourth quarter and fiscal year ended December 31, 2004.

A Form 8-K (Item 12) was filed on March 22, 2005 regarding a press release announcing that AVANT had promoted M. Timothy Cooke, Ph.D. as its Chief Operating Officer.

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#### **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 10, 2005 /s/ Una S. Ryan

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

Dated: May 10, 2005 /s/ Avery W. Catlin

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

## EXHIBIT INDEX

Exhibit No.	Description
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
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#### **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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (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

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(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: May 10, 2005

By: /s/ Una S. Ryan
Name: Una S. Ryan, Ph.D.

Title: President and Chief Executive Officer

#### CERTIFICATION

#### I, Avery W. Catlin, certify that:

- 1. I have reviewed this report on Form 10-Q of AVANT Immunotherapeutics, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (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

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(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: May 10, 2005 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: May 10, 2005 By: /s/ Una S. Ryan

Date: May 10, 2005

Name: Una S. Ryan, Ph.D.

Title: President and Chief Executive Officer

By: /s/ Avery W. Catlin

Name: Avery W. Catlin

Title: Senior Vice President and Chief Financial Officer