

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

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

For the quarterly period ended September 30, 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**  
(State of Incorporation)

**No. 13-3191702**  
(I.R.S. Employer Identification No.)

**119 Fourth Avenue, Needham, Massachusetts 02494-2725**  
(Address of principal executive offices) (Zip Code)

**(781) 433-0771**  
(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 126-2 of the Exchange Act). Yes  No .

As of November 3, 2005, 74,161,232 shares of common stock, \$.001 par value per share, were outstanding.

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FORM 10-Q  
Quarter Ended September 30, 2005  
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**AVANT IMMUNOTHERAPEUTICS, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**(Unaudited)**

	September 30, 2005	December 31, 2004
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$ 22,198,775	\$ 31,741,494
Accounts Receivable	5,643,420	2,230,350
Prepaid Expenses and Other Current Assets	750,714	567,916
<b>Total Current Assets</b>	<b>28,592,909</b>	<b>34,539,760</b>
Property and Equipment, Net	5,119,239	4,164,292
Intangible and Other Assets	5,315,851	6,063,185
Goodwill	1,036,285	1,036,285
<b>Total Assets</b>	<b>\$ 40,064,284</b>	<b>\$ 45,803,522</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$ 476,868	\$ 1,752,313
Accrued Expenses	2,891,573	3,500,422
Current Portion of Deferred Revenue	12,497	11,704
Current Portion of Long-Term Liabilities	204,674	186,509
<b>Total Current Liabilities</b>	<b>3,585,612</b>	<b>5,450,948</b>
Deferred Revenue	10,000,000	—
Long-Term Liabilities	1,790,552	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; 74,381,551 Issued and 74,161,232 Outstanding at September 30, 2005 and 74,351,571 Issued and 74,131,252 Outstanding at December 31, 2004	74,381	74,351
Additional Paid-In Capital	258,134,160	257,829,824
Deferred Compensation	(1,400,000)	(1,493,000)
Less: 220,319 Common Treasury Shares at Cost	(227,646)	(227,646)
Accumulated Deficit	(231,892,775)	(217,775,903)
<b>Total Stockholders' Equity</b>	<b>24,688,120</b>	<b>38,407,626</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 40,064,284</b>	<b>\$ 45,803,522</b>

*See accompanying notes to unaudited consolidated financial statements*

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

**Three Months Ended**  
**September 30,                      September 30,**

	2005	2004
<b>REVENUE:</b>		
Product Development and Licensing Agreements	\$ 78,692	\$ 144,280
Government Contracts and Grants	767,630	334,166
Product Royalties	—	49,064
<b>Total Revenue</b>	<b>846,322</b>	<b>527,510</b>
<b>OPERATING EXPENSE:</b>		
Research and Development	3,591,334	2,805,813
General and Administrative	1,670,306	1,290,567
Amortization of Acquired Intangible Assets	248,778	248,778
<b>Total Operating Expense</b>	<b>5,510,418</b>	<b>4,345,158</b>
<b>Operating Loss</b>	<b>(4,664,096)</b>	<b>(3,817,648)</b>
Investment and Other Income, Net	149,662	120,417
<b>Net Loss</b>	<b>\$ (4,514,434)</b>	<b>\$ (3,697,231)</b>
<b>Basic and Diluted Net Loss Per Common Share</b>	<b>\$ (0.06)</b>	<b>\$ (0.05)</b>
<b>Weighted Average Common Shares Outstanding</b>	<b>74,145,814</b>	<b>74,118,314</b>

*See accompanying notes to unaudited consolidated financial statements*

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	Nine Months Ended	
	September 30, 2005	September 30, 2004
<b>REVENUE:</b>		
Product Development and Licensing Agreements	\$ 209,209	\$ 2,393,118
Government Contracts and Grants	2,156,680	1,928,712
Product Royalties	88,146	129,388
<b>Total Revenue</b>	<b>2,454,035</b>	<b>4,451,218</b>
<b>OPERATING EXPENSE:</b>		
Research and Development	11,052,944	9,626,816
General and Administrative	5,242,185	3,852,413
Amortization of Acquired Intangible Assets	746,334	746,334
<b>Total Operating Expense</b>	<b>17,041,463</b>	<b>14,225,563</b>
<b>Operating Loss</b>	<b>(14,587,428)</b>	<b>(9,774,345)</b>
Investment and Other Income, Net	470,556	268,967
<b>Net Loss</b>	<b>\$ (14,116,872)</b>	<b>\$ (9,505,378)</b>
<b>Basic and Diluted Net Loss Per Common Share</b>	<b>\$ (0.19)</b>	<b>\$ (0.13)</b>
<b>Weighted Average Common Shares Outstanding</b>	<b>74,136,931</b>	<b>72,510,640</b>

*See accompanying notes to unaudited consolidated financial statements*

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

	Nine Months Ended	
	September 30, 2005	September 30, 2004
<b>Cash Flows from Operating Activities:</b>		
Net Loss	\$ (14,116,872)	\$ (9,505,378)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	1,142,620	1,045,078
Amortization of Deferred Compensation	363,000	207,000
Changes in Operating Assets and Liabilities:		

Accounts Receivable	1,586,930	1,199,685
Prepaid and Other Current Assets	(182,798)	(185,532)
Accounts Payable and Accrued Expenses	(1,884,293)	1,750,104
Deferred Revenue	5,000,793	(1,323,257)
<b>Net Cash Used in Operating Activities</b>	<b>(8,090,620)</b>	<b>(6,812,300)</b>
<b>Cash Flows from Investing Activities:</b>		
Acquisition of Property and Equipment	(1,351,233)	(1,557,782)
Proceeds from the Maturity of Marketable Securities	$\frac{3}{4}$	2,000,000
Purchases of Marketable Securities	$\frac{3}{4}$	(2,000,000)
Other Non-Current Assets	1,000	(10,231)
<b>Net Cash Used in Investing Activities</b>	<b>(1,350,233)</b>	<b>(1,568,013)</b>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from Stock Issuance	5,438	23,050,977
Proceeds from Exercise of Stock Options and Warrants	28,928	306,629
Payment of Long-Term Liabilities	(136,232)	$\frac{3}{4}$
<b>Net Cash Provided by (Used in) Financing Activities</b>	<b>(101,866)</b>	<b>23,357,606</b>
<b>Net Increase (Decrease) in Cash and Cash Equivalents</b>	<b>(9,542,719)</b>	<b>14,977,293</b>
<b>Cash and Cash Equivalents at Beginning of Period</b>	<b>31,741,494</b>	<b>18,251,044</b>
<b>Cash and Cash Equivalents at End of Period</b>	<b>\$ 22,198,775</b>	<b>\$ 33,228,337</b>
<b>Supplemental Disclosure of Noncash Financing Activities</b>		
Note payable from MassDevelopment	$\frac{3}{4}$	\$ 342,700
<b>Supplemental Disclosure of Cash Flow Information</b>		
Cash paid for interest	\$ 89,894	$\frac{3}{4}$

See Note 5.

See accompanying notes to unaudited consolidated financial statements

**AVANT IMMUNOTHERAPEUTICS, INC.**  
**Notes to Unaudited Consolidated Financial Statements**  
**September 30, 2005**

**(1) Nature of Business**

AVANT Immunotherapeutics, Inc. (the "Company" or "AVANT") 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 regions where infectious diseases are endemic and a proprietary vaccine candidate for cholesterol management. In addition, the Company is developing the VitriLife<sup>®</sup> preservation technology for use in manufacturing 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 and nine months ended September 30, 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 September 30, 2005, results of operations for the three months and nine months ended September 30, 2005 and 2004, and cash flows for the nine-month periods ended September 30, 2005 and 2004. The results of operations for the nine-month period ended September 30, 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 the Company believes 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**

On June 2, 2005, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 154, *Accounting Changes and Error Corrections* (FAS 154), which will require entities that voluntarily make a change in accounting principle to apply that change retrospectively to prior periods' financial statements, unless that would be impracticable. FAS 154 supersedes Accounting Principles Board Opinion No. 20, *Accounting Changes* (APB 20), which previously required that most voluntary changes in accounting principle be recognized by including in the current period's net income the cumulative effect of changing to the new accounting principle. FAS 154 also makes a distinction between "retrospective application" of an accounting principle and the "restatement" of financial statements to reflect the correction of an error. Another significant change in practice under the FAS 154 will be that if an entity changes its method of depreciation, amortization, or depletion for long-lived, non-financial assets, the change must be accounted for as a change in accounting estimate. Under APB 20, such a change would

have been reported as a change in accounting principle. FAS 154 applies to accounting changes and error corrections that are made in fiscal years beginning after December 15, 2005.

**(4) Paul Royalty Fund**

In May 2005, AVANT entered into an agreement whereby an affiliate of Paul Royalty Fund II, L.P. ("PRF") purchased an interest in the net royalties AVANT will receive on worldwide sales of Rotarix<sup>®</sup>. Rotarix<sup>®</sup> is licensed to GlaxoSmithKline plc ("Glaxo"). The terms of the agreement with PRF include an upfront unconditional payment from PRF totaling \$10 million (\$5 million paid at closing and \$5 million due on December 1, 2005) and the following milestone payments: (i) \$40 million on product launch in the European Union, and (ii) between \$9 million and \$11 million on product launch in the United States, depending on date of the launch.

In addition, AVANT retains some participation in the worldwide net royalty stream from Rotarix<sup>®</sup>. If worldwide net royalties on sales of Rotarix<sup>®</sup> from Glaxo exceed \$27.5 million in any year, AVANT will receive 92.5% of royalties in excess of \$27.5 million. Also, once PRF receives cumulative royalties equal to 2.45 times PRF's aggregate cash payments to AVANT, then AVANT will receive 92.5% of all additional royalties. If Rotarix<sup>®</sup> is not launched in the U.S. by the end of 2009, either PRF or AVANT can opt out of the U.S. portion of the agreement, and AVANT will retain all U.S.-derived royalties and PRF would not be obligated to make payments to AVANT upon U.S. approval.

The PRF transaction qualifies as a sale in accordance with guidance in EITF 88-18 "Sale of Future Revenues". The upfront unconditional payment of \$10 million was recorded by AVANT as deferred revenue at September 30, 2005. Any future milestone payments received from PRF will also be recorded as deferred revenue. Revenues will be recognized and calculated based on the ratio of total royalties received from Glaxo and remitted to PRF over expected total amounts to be received by PRF and then applying this percentage to the total cumulative consideration received from PRF to date. The expected total of payments to be paid to PRF is an estimate which AVANT will update from time to time to determine that the estimate continues to be reasonable in the light of then current events and circumstances.

**(5) 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.

On September 21, 2005, AVANT awarded Dr. Una Ryan, its President and CEO, 200,000 Restricted Stock Units. The Restricted Stock Units vest over four years but will vest in their entirety upon the earlier of the sale of the Company or Dr. Ryan's retirement at or after age 65. The Company determined the value of the Restricted Stock Units to be \$270,000, based on a valuation of \$1.35 per share, the closing price of AVANT's common stock on the award date. The value of the Restricted Stock Units is being amortized over approximately two years until Dr. Ryan attains age 65, and is being recorded as compensation expense.

In November 2004 and September 2003, the Company also awarded Restricted Stock Units to Dr. Ryan 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 September 30, 2005

and 2004, respectively and \$363,000 and \$207,000 as stock-based compensation expense in the statement of operations during the nine-month periods ended September 30, 2005 and 2004, respectively.

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

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Net Loss:				
As reported	\$ 4,514,434	\$ 3,697,231	\$ 14,116,872	\$ 9,505,378
Less: Stock-based employee compensation expense as reported	(121,000)	(69,000)	(363,000)	(207,000)
Add: Total stock-based employee compensation expense determined under fair value based method for all awards	221,412	251,800	728,636	729,100
Pro forma	\$ 4,614,846	\$ 3880,031	\$ 14,482,508	\$ 10,027,478

**Basic and Diluted Net Loss Per Share:**

As reported	\$	0.06	\$	0.05	\$	0.19	\$	0.13
Pro forma	\$	0.06	\$	0.05	\$	0.20	\$	0.14

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

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Expected stock price volatility	81%	81%	81%	64%
Expected option term	4.5 Years	5 Years	4.5 Years	5 Years
Risk-free interest rate	3.8 - 4.3%	3.3 - 3.9%	3.6 - 4.3%	2.7 - 4.2%
Expected dividend yield	None	None	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.

**(6) 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:

	September 30, 2005	December 31, 2004
Trade Receivables	\$ 5,614,458	\$ 2,205,176
Other Receivables	28,962	25,174
	<u>\$ 5,643,420</u>	<u>\$ 2,230,350</u>

Other receivables at September 30, 2005 and December 31, 2004 primarily represent interest receivable from a bank.

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**(7) Property and Equipment**

Property and equipment includes the following:

	September 30, 2005	December 31, 2004
Laboratory Equipment	\$ 2,824,559	\$ 2,390,458
Manufacturing Equipment	534,760	—
Office Furniture and Equipment	1,864,023	1,665,401
Leasehold Improvements	4,613,988	1,704,590
Construction in Progress	747,932	3,473,580
Property and Equipment, Total	10,585,262	9,234,029
Less Accumulated Depreciation and Amortization	(5,466,023)	(5,069,737)
	<u>\$ 5,119,239</u>	<u>\$ 4,164,292</u>

**(8) Intangible and Other Assets**

Intangible and other assets include the following:

	Estimated Lives	September 30, 2005			December 31, 2004		
		Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
<b>Intangible Assets:</b>							
Collaborative Relationships	5 years	\$ 1,090,000	\$ (1,090,000)	\$ —	\$ 1,090,000	\$ (1,090,000)	\$ —
Core Technology	10 years	3,786,900	(1,413,680)	2,373,220	3,786,900	(1,129,658)	2,657,242
Developed Technology	7 years	3,263,100	(2,250,400)	1,012,700	3,263,100	(1,901,200)	1,361,900
Strategic Partner Agreement	17 years	2,563,900	(728,950)	1,834,950	2,563,900	(615,838)	1,948,062
Total Intangible Assets		10,703,900	(5,483,030)	5,220,870	10,703,900	(4,736,696)	5,967,204
Other Non Current Assets		94,981	¾	94,981	95,981	¾	95,981
		<u>\$ 10,798,881</u>	<u>\$ (5,483,030)</u>	<u>\$ 5,315,851</u>	<u>\$ 10,799,881</u>	<u>\$ (4,736,696)</u>	<u>\$ 6,063,185</u>

All of the Company's intangible assets are amortized over their estimated useful lives. Total amortization expense for intangible assets was \$248,778 and \$746,334 for the three- and nine-month periods ended September 30, 2005 and 2004, respectively.

The estimated future amortization expense of intangible assets as of September 30, 2005 for the remainder of fiscal year 2005 and the five succeeding years is as follows:

Year ending December 31,	Estimated Amortization Expense
2005 (remaining three months)	\$ 248,778
2006	995,112

2007	960,212
2008	529,512
2009	529,512
2010	514,622

**(9) 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.

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Potentially dilutive securities include stock options, warrants and restricted stock units. Options and warrants to purchase 3,549,365 and 3,536,242 shares of common stock and restricted stock units totaling 1,000,000 and 400,000 shares were not included in the computations of weighted average common shares for the periods ended September 30, 2005 and 2004, respectively, because inclusion of such shares would have an anti-dilutive effect on net loss per share.

**(10) 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 nine-month periods ended September 30, 2005 and 2004 were \$209,209 and \$2,393,118, respectively. A summary of these contracts follows:

*(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 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 Cincinnati Children's Hospital Medical Center ("CCH") with respect to this agreement and incurred licensing fees of \$200,000 in 2004. 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 achievement of specific milestones. AVANT licensed-in the Rotarix® technology in 1995 and owes a license fee of 30% to CCH on net royalties received from Glaxo. In May 2005, AVANT entered into an agreement whereby an affiliate of Paul Royalty Fund II, L.P. ("PRF") purchased an interest in the net royalties AVANT will receive on worldwide sales of Rotarix® (see Note 4). Under the PRF agreement, AVANT will retain 50% of future Glaxo milestone payments, with the balance payable to PRF and CCH.

*(B) Pfizer Inc ("Pfizer")*

In connection with the Company's acquisition of Megan in 2000, 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. On August 5, 2005, AVANT received notice from DVC of termination of the license agreement, effective November 5, 2005.

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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 September 30, 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 awarded by 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 bringing the aggregate funding commitments for this vaccine development program to approximately \$10 million. 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 nine months ended September 30, 2005 and 2004, AVANT recognized \$1,942,709 and \$1,837,628, respectively, in government contract revenue from DVC. Through September 30, 2005, AVANT had received approximately \$7.4 million in payments under the various 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 entered into 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 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.

**(11) Long-Term Liabilities and Deferred Revenue**

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 September 30, 2005, AVANT has recorded leasehold improvement assets of \$1,227,800 and currently has a loan payable of \$1,166,410 to MassDevelopment, of which \$81,853 is classified as current and \$1,084,557 as long-term. AVANT began amortizing the leasehold improvement assets this quarter when the Fall River facility became 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 \$868,600 at September 30, 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”). 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 September 30, 2005, AVANT has recorded manufacturing and laboratory equipment assets of \$903,657 and currently has a note payable of \$828,815 to MassDevelopment, of which \$122,820 is classified as current and \$705,995 as long-term. AVANT began depreciating the manufacturing and laboratory equipment assets over the estimated economic lives of the assets this quarter when the Fall River facility became operational. 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 \$738,600 at September 30, 2005.

*(C) Deferred Revenue*

At June 30, 2005, AVANT recorded the upfront unconditional payments totaling \$10 million from an affiliate of Paul Royalty Fund II, L.P. (“PRF”) as deferred revenue. Any future milestone payments received from PRF will also initially be recorded as deferred revenue. Deferred revenue will be amortized to revenue as described in Note 4.

**(12) Commitments and Contingencies**

*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. AVANT has entered into a number of amendments to the Lonza Agreement for specific process development and scale-up work and remaining aggregate commitments as of September 30, 2005 total approximately \$657,524. The Company has incurred \$1,287,651 and \$6,563,263, respectively, of expense related to the Lonza Agreement in the nine-month period ended September 30, 2005 and from inception through September 30, 2005, of which \$68,749 remained accrued at September 30, 2005.

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**Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995:** This quarterly report on Form 10-Q includes forward-looking statements that are subject to a variety of risks and uncertainties and reflect AVANT’s current views with respect to future events and financial performance. There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statements made by AVANT. These factors include, but are not limited to: (1) the integration of multiple technologies and programs; (2) the ability to adapt AVANT’s vectoring systems to develop new, safe and effective orally administered vaccines against anthrax and plague or any other microbes used as bioweapons and other disease causing agents; (3) the ability to successfully complete development and commercialization of TP10, 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 Rotarix® in major commercial markets, as well as the timing and success of worldwide commercialization of Rotarix® by our partner, GlaxoSmithKline; (9) Glaxo’s strategy and business plans to launch and supply Rotarix® worldwide, including in the US and other major markets; (10) changes in existing and potential relationships with corporate collaborators; (11) the availability, cost, delivery and quality of clinical and commercial grade materials supplied by contract manufacturers; (12) 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; (13) the ability to obtain substantial additional funding; (14) the ability to develop and commercialize products before competitors and that are superior to the alternatives developed by competitors; (15) the ability to

retain certain members of management; and (16) 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.

*Long-Lived Assets:* In the ordinary course of our business, we incur substantial costs to construct property and equipment. The treatment of costs to construct these assets depends on the nature of the costs and the stage of construction. Costs incurred in the project planning and design phase, and in the construction and installation phase, are capitalized as part of the cost of the asset. We stop capitalizing costs when the asset is substantially complete and ready for its intended use. Determining the appropriate period during which to capitalize costs, and assessing whether particular costs qualify for capitalization, requires us to make significant judgments. These judgments can have a material impact on our reported results.

For manufacturing property and equipment, we also capitalize the cost of validating these assets for the underlying manufacturing process. We complete the capitalization of validation costs when the asset is substantially complete and ready for its intended use. Costs capitalized include incremental labor and fringe benefits, and direct consultancy services. Determining whether to capitalize validation costs require judgment and can have a material impact on our reported results.

Property and equipment is stated at cost and depreciated over the estimated useful lives of the related assets using the straight-line method. Laboratory equipment and office furniture and equipment are depreciated over a five year period and computer equipment is depreciated over a three year period. Manufacturing equipment is amortized over a seven to ten year period. Leasehold improvements are amortized over the shorter of the estimated useful life or the noncancelable term of the related lease. Property and equipment under construction is classified as construction in progress and is depreciated or amortized only after the asset is placed in service. Determining the economic lives of property and equipment requires us to make significant judgments that can materially impact our operating results.

**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 gives 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 and is being targeted for marketing by Glaxo worldwide. 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.

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 bacterial vector delivery technologies with the unique VitriLife® manufacturing process represent the potential for a new generation of vaccines. In addition, AVANT’s vaccine technologies 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.

**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 nine months ended September 30, 2005, AVANT incurred an aggregate of \$11.1 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 nine-month periods ended September 30, 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.

	Nine Months Ended September 30,		Years Ended December 31,	
<i>Bacterial Vaccines:</i>	2005	2004	2004	2003

CholeraGarde <sup>®</sup>	\$ 707,500	\$ 80,700	\$ 123,100	\$ 695,800
Ty800	334,900	545,900	688,300	186,300
Other	348,300	233,300	332,500	137,500
<b>BioDefense Vaccines:</b>	<b>1,839,200</b>	<b>2,634,700</b>	<b>3,082,800</b>	<b>3,524,500</b>
<b>Cholesterol Management Vaccine:</b>				
CETi-1	458,500	621,900	816,900	3,404,000
<b>Complement Inhibitors:</b>				
TP10/TP20	6,973,000	4,906,000	7,706,300	1,648,700
<b>Food Safety &amp; Animal Health Vaccines:</b>	<b>7,000</b>	<b>11,600</b>	<b>12,600</b>	<b>49,400</b>
<b>Viral Vaccines:</b>				
Rotarix <sup>®</sup> vaccine	¾	150,000	500,000	200,000
Therapore <sup>®</sup> /HIV	4,900	196,800	184,900	72,400
<b>Other Programs:</b>	<b>379,700</b>	<b>263,800</b>	<b>426,400</b>	<b>102,700</b>
<b>Total R&amp;D Expense</b>	<b>\$ 11,053,000</b>	<b>\$ 9,644,700</b>	<b>\$ 13,873,800</b>	<b>\$ 10,021,300</b>

## 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. Glaxo gained approval for Rotarix<sup>®</sup> 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 has launched 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. Glaxo has agreed to make further payments, which could total up to \$5.5 million, upon achievement of specific milestones. AVANT licensed-in the Rotarix<sup>®</sup> technology in 1995 and owes a license fee of 30% to CCH on net royalties received from Glaxo. In May 2005, AVANT entered into an agreement whereby an affiliate of PRF purchased an interest in the net royalties AVANT will receive on worldwide sales of Rotarix<sup>®</sup> (see Note 4 of our unaudited consolidated financial statements). Under the PRF agreement, AVANT will retain 50% of future Glaxo milestone payments, with the balance payable to PRF and CCH.

**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, but, with no 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 treatment effect that TP10 has for women undergoing high risk cardiac surgery, as well as augment the safety data for that patient population to allow for the design of a subsequent registration-directed trial. In October 2005, AVANT completed enrollment in this trial and expects to report results of this study in the first quarter of 2006. 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 nine months

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ended September 30, 2005, the Company incurred approximately \$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<sup>®</sup>, a technology with the potential to reduce manufacturing costs and improve product stability, eliminating the need for vaccine refrigeration during shipping and storage. With this technology and AVANT's *Cholera*- and *Salmonella*-vectored delivery technologies, named VibrioVec<sup>®</sup> and SalmoVec<sup>™</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<sup>®</sup> 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. In July 2005, Bangladesh study results in children and infants showed CholeraGarde<sup>®</sup> to be well tolerated and highly immunogenic, with 77% of children aged 9 months to 5 years generating protective immune responses. Previously published results showed the vaccine to be well tolerated and immunogenic against the cholera organism in the adult portion of this trial.

In July 2005, AVANT reported that it and Harvard Medical School would receive approximately \$500,000 from the National Institutes of Health to apply AVANT's VitriLife<sup>®</sup> formulation to CholeraGarde<sup>®</sup>. In the future, AVANT plans to utilize VitriLife<sup>®</sup>, a proprietary technology that confers thermostability to live bacterial vaccines, at the Fall River facility for its other bacterial vaccines.

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<sup>®</sup> program. During the nine months ended September 30, 2005, AVANT incurred approximately \$707,500 in research, development and clinical costs on its CholeraGarde<sup>®</sup> 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 the first quarter of 2006. 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 nine months ended September 30, 2005, AVANT incurred approximately \$334,900 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. In April 2005, AVANT was awarded a Phase I Small Business Innovation Research (SBIR) grant to support the development of a live attenuated salmonella vaccine against campylobacter. The NIAID award provides approximately \$131,000 in funding and work was started by AVANT during the third quarter of 2005. During the nine months ended September 30, 2005, AVANT incurred approximately \$348,300 in research, development and clinical costs on these pre-clinical programs.

*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.

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By engineering key disease antigens into the DNA of the vector organisms, AVANT expects to be able to extend the protective ability of its single-dose oral vaccines to a wide variety of illnesses. AVANT believes its vector technologies may prove useful for improving and expanding America’s vaccine arsenal against microbial agents used in war or terrorist attacks.

In October 2001, AVANT granted DynPort Vaccine Company LLC (“DVC”) a license for exclusive rights to use certain components of AVANT’s anthrax vaccine technology. In October 2002, DVC announced the initiation of a Phase I clinical trial of a new injectable recombinant anthrax vaccine in approximately 70 volunteers. The vaccine candidate consists of a highly purified protein—Protective Antigen—derived from the anthrax bacterium using recombinant DNA technology and production processes licensed from AVANT. The study will evaluate tolerability, safety and immunogenicity of DVC’s new vaccine. On August 5, 2005, AVANT received notice from DVC of termination of the license agreement, effective November 5, 2005. DVC plans to complete the ongoing Phase I clinical trial.

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 September 30, 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 awarded by 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 bringing aggregate funding commitments for this vaccine development program to approximately \$10 million. 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 nine months ended September 30, 2005 and 2004, AVANT recognized \$1,942,709 and \$1,837,628, respectively, in government contract revenue from DVC. Through September 30, 2005, AVANT had received approximately \$7.4 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 nine months ended September 30, 2005, AVANT incurred approximately \$1,839,200 in research and development costs on its biodefense vaccine program.

*Food Safety and Animal Health Vaccines:* AVANT has partnered with Pfizer Inc. (“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 nine months ended September 30, 2005, AVANT incurred approximately \$7,000 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 vaccine worked as designed to elicit anti-CETP antibodies in a high percentage of patients treated,

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approximately 90%. In recent pre-clinical testing, AVANT has identified a new adjuvanted formulation for the vaccine that elicits more than a 10-fold increase in anti-CETP antibody titers when compared to the current CETi vaccine. The Company has contracted for the production of GMP peptide for the newly 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 nine months ended September 30, 2005, AVANT incurred approximately \$458,500 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 or where certain uses of the technology are outside of AVANT’s focus. For example, when AVANT acquired Megan, it also signed an agreement with Pfizer 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.

*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 an initial license fee, milestone payments and royalties. In April 2004, AdProTech was acquired by Inflazyme Pharmaceuticals Ltd. which assumed the license.

## RESULTS OF OPERATIONS

### Three-Month Period Ended September 30, 2005 as Compared with the Three-Month Period Ended September 30, 2004

AVANT reported consolidated net loss of \$4,514,434, or \$.06 per share, for the third quarter ended September 30, 2005, compared with a net loss of \$3,697,231, or \$.05 per share, for the third quarter ended September 30, 2004. The weighted average common shares outstanding used to calculate net loss per common share was 74,145,814 in 2005 and 74,118,314 in 2004.

*Revenue:* Total revenue increased \$318,812 to \$846,322 for the third quarter of 2005 compared to \$527,510 for the third quarter of 2004.

Product development and licensing revenue decreased \$65,588, or 45.5%, to \$78,692 in 2005 from \$144,280 in 2004. Product development and licensing revenue in 2004 consisted primarily of 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 and NIH grants, AVANT recognized \$767,630 and \$334,166 in government contract and grant revenue during the third 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 remain level 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. In early March 2005, the USDA placed a stop sale order on Megan®Vac 1 and Megan®Egg for LAHI's failure to update the Outline of Production as LAHI improved the fermentation process. LAHI updated the Outline of Production and in July 2005 the USDA lifted the stop sale order on the Megan products. AVANT received no royalty payments during the third quarter of 2005 and received \$49,064 in the third quarter of 2004.

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*Operating Expense:* Total operating expense increased \$1,165,260, or 26.8%, to \$5,510,418 for the third quarter of 2005 compared to \$4,345,158 for the third quarter of 2004.

Research and development expense increased \$785,521, or 28%, to \$3,591,334 in 2005 from \$2,805,813 in 2004. The increase in 2005 compared to 2004 is primarily due to increases in TP10 clinical trials costs of \$481,663, increases in contract manufacturing costs of \$75,464 associated with the TP10 program and increased personnel, operating and facility-related costs of \$277,118 associated with operations at the Fall River manufacturing facility. These increases were offset in part by declines in, license fees of \$56,250. AVANT expects research and development expense to remain at current levels in the fourth quarter of 2005 as the TP10 Phase II female clinical trial finalizes, as AVANT's contract manufacturer continues process development and scale-up work for the TP10 program and as the Fall River facility runs at full operational status.

General and administrative expense increased \$379,739, or 29.4%, to \$1,670,306 in 2005 compared to \$1,290,567 in 2004 and is primarily attributed to increases in: personnel and related costs of \$75,743, legal fees of \$111,165 primarily related to patent matters, and other professional fees and consultancy costs of \$78,850 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 \$29,245 to \$149,662 for the third quarter of 2005 compared to \$120,417 for the third quarter of 2004. The increase is primarily due to higher interest rates, offset in part by lower average cash balances during the third quarter of 2005 compared to the third quarter of 2004. During the third quarters of 2005 and 2004, the average month-end cash balances were \$24,007,956 and \$36,502,328, respectively. The effective interest rates during the third quarters of 2005 and 2004 were 3.27% and 1.32%, respectively.

### Nine-Month Period Ended September 30, 2005 as Compared with the Nine-Month Period Ended September 30, 2004

AVANT reported a consolidated net loss of \$14,116,872, or \$.19 per share, for the nine months ended September 30, 2005, compared with a net loss of \$9,505,378, or \$.13 per share, for the nine months ended September 30, 2004. The increase in net loss between periods was due to reduced revenues and increased operating expenses, offset partially by increased investment and other income. The weighted average common shares outstanding used to calculate net loss per common share was 74,136,931 in 2005 and 72,510,640 in 2004.

*Revenue:* Total revenue decreased \$1,997,183 to \$2,454,035 for the first nine months of 2005 compared to \$4,451,218 for the first nine months of 2004.

Product development and licensing revenue decreased \$2,183,909 to \$209,209 for the first nine months of 2005 from \$2,393,118 for the first nine months of 2004. The decrease is primarily due to the one-time recognition of \$1 million in revenue from DVC for rPA clinical materials and a license fee of \$1 million from AdProTech, Ltd in the first quarter of 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 and NIH grants, AVANT recognized \$2,156,680 and \$1,928,712 in government contract and grant revenue during the first nine months of 2005 and 2004, respectively. AVANT expects the level of research work to be performed for DVC during the remainder of 2005 to approximate the level of research work performed during the first nine months of 2005.

In 2002, AVANT transferred the marketing and distribution of the Megan poultry product line to our partner, LAHI. Product royalty payments received by AVANT for Megan®Vac 1 and Megan®Egg product sales for the first nine months of 2005 and 2004 totaled \$88,146 and \$129,388, respectively.

*Operating Expense:* Total operating expense increased \$2,815,900, or 19.8%, to \$17,041,463 for the first nine months of 2005 compared to \$14,225,563 for the first nine months of 2004.

Research and development expense increased \$1,426,128, or 14.8%, to \$11,052,944 for the first nine months of 2005 compared to \$9,626,816 for the first nine months of 2004. The increase in 2005 compared to 2004 is primarily due to increases in contract manufacturing costs and lab supplies of \$819,907 associated with the TP10 program, to increases in clinical trial costs of \$367,138 and increased personnel, operating and facility-related costs of \$751,570 associated with operations of the Fall River facility. These increases were offset in part by decreases in consultancy costs of \$36,892, license fees of \$168,749, and insurance costs of \$56,742. AVANT expects research and development expense to continue at current levels for the remainder of 2005 as the TP10 Phase II female clinical trial finalizes, as AVANT's contract manufacturer continues process development and scale-up work and as the Fall River facility runs at full operational status.

General and administrative expense increased \$1,389,772, or 36.1%, to \$5,242,185 for the first nine months of 2005 compared to \$3,852,413 for the first nine months of 2004. The increase in 2005 is primarily attributed to increased: personnel and related expenses of \$431,546, legal fees of \$502,787 primarily associated with the PRF transaction and patent matters, and other professional services and consulting costs of \$305,572 related to project management and Sarbanes-Oxley compliance. AVANT expects the level of general and administrative expense during the remainder of 2005 to approximate the level of expense incurred during the first nine months of 2005 and 2004.

Amortization expense of acquired intangible assets was \$746,334 in the first nine months of 2005 and 2004.

*Investment Income, Net:* Net investment income increased \$201,589 to \$470,556 for the first nine months of 2005 compared to \$268,967 for the first nine months of 2004. The increase is primarily due to higher average interest rates, offset in part by lower average cash balances during the first nine months of 2005 compared to the first nine months of 2004. During the first nine months of 2005 and 2004, the average month-end cash balances were \$26,948,666 and \$36,938,225, respectively. The effective interest rates during the first nine months of 2005 and 2004 were 2.80% and 1.08%, respectively.

## LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2005, AVANT's principal sources of liquidity consisted of cash and cash equivalents of \$22,198,775. 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. The Company maintains cash balances with financial institutions in excess of insured limits, however, 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, laboratories and manufacturing facility, 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 \$8,090,620 for the first nine months of 2005 compared to \$6,812,300 for the first nine months of 2004. The increase is primarily attributed to an increase in net loss incurred in 2005 compared to 2004, a decrease in accounts payable and accrued expenses due to timing of payments, offset partly by the receipt of \$5 million from PRF which is included in deferred revenue related to the PRF royalty transaction. AVANT expects that cash used in operations will continue to increase in 2005 as the Company continues to develop its products in clinical trials, contracts 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 decreased to \$1,350,233 for the first nine months of 2005 compared to \$1,568,013 for the first nine months of 2004. The decrease is due to lower investment in property and equipment in 2005 compared to 2004 primarily at the Fall River manufacturing facility. AVANT expects it will continue to use cash in its investing activities as the Company expands its infrastructure and brings the Fall River facility to full operational status.

Net cash used in financing activities was \$101,866 for the first nine months of 2005 compared to net cash provided by financing activities of \$23,357,606 for the first nine months of 2004. The decrease in cash provided by financing activities between years is due primarily to the sale of common stock in the first quarter of 2004.

## AGGREGATE CONTRACTUAL OBLIGATIONS

The following table summarizes AVANT's contractual obligations at September 30, 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	2006-2008	2009-2010	Thereafter
<b>Contractual obligations:</b>					
Operating lease obligations	\$ 5,196,600	\$ 617,300	\$ 4,041,100	\$ 538,200	\$ —
Loan Payable*	1,632,800	24,400	418,600	256,200	933,600
Note Payable*	962,700	29,500	531,500	354,300	47,400
Licensing obligations	531,300	21,300	255,000	170,000	85,000
Total contractual obligations	\$ 8,323,400	\$ 692,500	\$ 5,246,200	\$ 1,318,700	\$ 1,066,000
<b>Commercial commitments:</b>					
Clinical development	\$ 1,786,800	\$ 1,786,800	\$ —	\$ —	\$ —
Manufacturing development	657,500	287,300	370,200	—	—
Total commercial commitments	\$ 2,444,300	\$ 2,074,100	\$ 370,200	\$ —	\$ —

\* 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 September 30, 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 September 30, 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 September 30, 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**

#### **(a) Exhibits**

- 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 August 3, 2005 regarding a press release announcing that AVANT had reported its financial results for the second quarter ended June 30, 2005.

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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: November 3, 2005

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

Dated: November 3, 2005

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

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
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;
  - (c) 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
  - (d) 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: November 3, 2005

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

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CERTIFICATION

I, Avery W. Catlin, 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;
  - (c) 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
  - (d) 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: November 3, 2005

By:     /s/ Avery W. Catlin    

Name: Avery W. Catlin

Title: Senior Vice President and  
Chief Financial Officer

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

Date: November 3, 2005

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

Date: November 3, 2005

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