

**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 June 30, 2004

OR

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

Commission file number: 0-15006

AVANT IMMUNOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of Incorporation)

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

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

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

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

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

As of July 30, 2004, 74,328,100 shares of common stock, \$.001 par value per share, were outstanding.

AVANT IMMUNOTHERAPEUTICS, INC.

FORM 10-Q

Quarter Ended June 30, 2004

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

**AVANT IMMUNOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEET
June 30, 2004 and December 31, 2003
(Unaudited)**

	June 30, 2004	December 31, 2003
ASSETS		
Current Assets:		
Cash and Cash Equivalents	\$ 39,370,700	\$ 20,251,000
Accounts Receivable	540,100	1,472,800
Prepaid Expenses and Other Current Assets	290,300	585,200
Total Current Assets	40,201,100	22,309,000
Property and Equipment, Net	1,113,200	912,700
Intangible and Other Assets	6,549,500	7,047,100
Goodwill	1,036,300	1,036,300
Total Assets	\$ 48,900,100	\$ 31,305,100
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 307,900	\$ 475,800
Accrued Expenses	2,764,100	1,453,400
Current Portion Deferred Revenue	257,300	1,456,200
Total Current Liabilities	3,329,300	3,385,400
Stockholders' Equity:		
Convertible Preferred Stock, 4,513,102 Shares Authorized; None Issued and Outstanding at June 30, 2004 and December 31, 2003	—	—
Common Stock, \$.001 Par Value; 100,000,000 Shares Authorized; 74,322,900 Issued and 74,102,600 Outstanding at June 30, 2004 and 64,928,400 Issued and 64,708,100 Outstanding at December 31, 2003	74,300	64,900
Additional Paid-In Capital	256,955,400	233,643,500
Deferred Compensation	(851,000)	(989,000)
Less: 220,300 Common Treasury Shares at Cost at June 30, 2004 and December 31, 2003	(227,600)	(227,600)
Accumulated Deficit	(210,380,300)	(204,572,100)
Total Stockholders' Equity	45,570,800	27,919,700
Total Liabilities and Stockholders' Equity	\$ 48,900,100	\$ 31,305,100

See accompanying notes to unaudited consolidated financial statements

**AVANT IMMUNOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF OPERATIONS
For the Three Months Ended June 30, 2004 and 2003
(Unaudited)**

	June 30, 2004	June 30, 2003
REVENUE:		

Product Development and Licensing Agreements	\$ 124,400	\$ 187,000
Government Contracts and Grants	714,700	849,300
Product Royalties	53,900	42,100
Total Revenue	893,000	1,078,400
OPERATING EXPENSE:		
Research and Development	3,367,800	2,673,400
General and Administrative	1,269,700	1,351,700
Amortization of Acquired Intangible Assets	248,800	248,800
Total Operating Expense	4,886,300	4,273,900
Operating Loss	(3,993,300)	(3,195,500)
Investment Income, Net	94,500	12,200
Net Loss	\$ (3,898,800)	\$ (3,183,300)
Basic and Diluted Net Loss Per Common Share	\$ (0.05)	\$ (0.05)
Weighted Average Common Shares Outstanding	74,091,600	60,468,700

See accompanying notes to unaudited consolidated financial statements

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AVANT IMMUNOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF OPERATIONS
For the Six Months Ended June 30, 2004 and 2003
(Unaudited)

	June 30, 2004	June 30, 2003
REVENUE:		
Product Development and Licensing Agreements	\$ 2,248,800	\$ 333,800
Government Contracts and Grants	1,594,600	1,348,900
Product Royalties	80,300	77,400
Total Revenue	3,923,700	1,760,100
OPERATING EXPENSE:		
Research and Development	6,821,000	5,365,900
General and Administrative	2,561,800	2,576,400
Amortization of Acquired Intangible Assets	497,600	497,600
Total Operating Expense	9,880,400	8,439,900
Operating Loss	(5,956,700)	(6,679,800)
Investment Income, Net	148,500	134,300
Net Loss	\$ (5,808,200)	\$ (6,545,500)
Basic and Diluted Net Loss Per Common Share	\$ (0.08)	\$ (0.11)
Weighted Average Common Shares Outstanding	71,655,100	60,468,700

See accompanying notes to unaudited consolidated financial statements

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AVANT IMMUNOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
For the Six Months Ended June 30, 2004 and 2003
(Unaudited)

	June 30, 2004	June 30, 2003
Cash Flows from Operating Activities:		

Net Loss	\$ (5,808,200)	\$ (6,545,500)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:	836,100	890,000
Depreciation and Amortization		
Changes in Assets and Liabilities:		
Accounts Receivable	932,700	(354,900)
Prepaid and Other Current Assets	294,900	93,300
Accounts Payable and Accrued Expenses	1,142,800	(594,100)
Deferred Revenue	(1,198,900)	776,200
Net Cash Used in Operating Activities	(3,800,600)	(5,735,000)
Cash Flows from Investing Activities:		
Acquisition of Property and Equipment	(401,000)	(157,900)
Increase in Patents	¾	(105,800)
Cash Paid for Acquisition of Universal Preservation Technologies, Inc. Assets	¾	(2,000,000)
Net Cash Used in Investing Activities	(401,000)	(2,263,700)
Cash Flows from Financing Activities:		
Proceeds from Stock Issuance	23,051,000	¾
Proceeds from Exercise of Stock Options and Warrants	270,300	3,400
Purchases of Treasury Stock	¾	(91,300)
Net Cash Provided by (Used In) Financing Activities	23,321,300	(87,900)
Increase (Decrease) in Cash and Cash Equivalents	19,119,700	(8,086,600)
Cash and Cash Equivalents at Beginning of Period	20,251,000	25,070,700
Cash and Cash Equivalents at End of Period	\$ 39,370,700	\$ 16,984,100

See accompanying notes to unaudited consolidated financial statements

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

(1) Nature of Business

AVANT Immunotherapeutics, Inc. is engaged in the discovery, development and commercialization of products that harness the human immune system to prevent and treat disease. The Company is developing a broad portfolio of vaccines and therapeutics against cardiovascular, viral and bacterial diseases, including single-dose oral vaccines aimed at protecting travelers and people in endemic regions from cholera, typhoid fever and other illnesses. In addition, the Company is conducting clinical studies of a treatment to reduce complement-mediated tissue damage associated with cardiac by-pass surgery, and a proprietary vaccine candidate for cholesterol management. AVANT further leverages the value of its technology portfolio through corporate partnerships. Current collaborations encompass the development of an oral human rotavirus vaccine, vaccines to combat threats of biological warfare, and vaccines addressed to human food safety and animal health.

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

(2) Interim Financial Statements

The accompanying unaudited consolidated financial statements for the three months and six months ended June 30, 2004 and 2003 include the consolidated accounts of AVANT, and have been prepared in accordance with instructions to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, the information contained herein reflects all adjustments, consisting solely of normal recurring adjustments, that are necessary to present fairly the Company's financial position at June 30, 2004, results of operations for the three- and six-month periods ended June 30, 2004 and 2003, and cash flows for the six-month periods ended June 30, 2004 and 2003. The results of operations for the three- and six-month periods ended June 30, 2004 are not necessarily indicative of results for any future interim period or for the full year.

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

(3) Property and Equipment

Property and equipment includes the following:

	June 30, 2004	December 31, 2003
Laboratory Equipment	\$2,452,700	\$2,422,100
Manufacturing Equipment	242,300	¾

Office Furniture and Equipment	1,668,900	1,633,500
Leasehold Improvements	1,761,100	1,668,400
Property and Equipment, Total	6,125,000	5,724,000
Less Accumulated Depreciation and Amortization	(5,011,800)	(4,811,300)
	<u>\$1,113,200</u>	<u>\$ 912,700</u>

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(4) **Intangible and Other Assets**

Intangible and other assets include the following:

	<u>Estimated Lives</u>	<u>June 30, 2004</u>	<u>December 31, 2003</u>
Intangible Assets:			
Collaborative Relationships	5 years	1,090,000	1,090,000
Core Technology	10 years	3,786,900	3,786,900
Developed Technology	7 years	3,263,100	3,263,100
Strategic Partner Agreement	17 years	2,563,900	2,563,900
Accumulated Amortization		<u>(4,239,200)</u>	<u>(3,741,600)</u>
Intangible Assets, Net		6,464,700	6,962,300
Other Non Current Assets			
		84,800	84,800
		<u>\$ 6,549,500</u>	<u>\$ 7,047,100</u>

All of our intangible assets are amortized over their useful lives. Total amortization expense for intangible assets was \$248,800 and \$497,600 for the three- and six-month periods ended June 30, 2004 and 2003.

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

<u>Year ending December 31,</u>	<u>Estimated Amortization Expense</u>
2004 (remaining six months)	\$ 497,600
2005	995,100
2006	995,100
2007	956,300
2008	529,500
2009	529,500

(5) **Net Income (Loss) Per Share**

Consistent with SFAS 128, basic earnings (loss) per share amounts are based on the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share amounts are based on the weighted average number of shares of common stock and the potential common stock outstanding during the period. We have excluded all of the potential common stock shares from the calculation of diluted weighted average share amounts for the three-month and six-month periods ended June 30, 2004 and 2003 as its inclusion would have been anti-dilutive. A total of 3,472,000 and 5,215,800 stock options and warrants were excluded from the computation of weighted average common shares for the periods ended June 30, 2004 and 2003, respectively, as they were anti-dilutive.

(6) **Stock Options**

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

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

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	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2004</u>	<u>2003</u>	<u>2004</u>	<u>2003</u>
Net Loss:				
As reported	\$ 3,898,800	\$ 3,183,300	\$ 5,808,200	\$ 6,545,500
Add: Stock-based employee compensation expense as reported	69,000	¾	138,000	¾
Less: Total stock-based employee compensation expense determined under fair value based method for all awards	(168,000)	(206,800)	(339,400)	(432,900)
Pro forma	<u>4,135,800</u>	<u>3,390,100</u>	<u>6,285,600</u>	<u>6,978,400</u>
Basic and Diluted Net Loss Per Share:				
As reported	\$ 0.05	\$ 0.05	\$ 0.08	\$ 0.11

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 June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Expected stock price volatility	109%	109%	109%	109%
Expected option term	5 Years	2.5 Years	5 Years	2.5 Years
Risk-free interest rate	3.1 - 4.2%	1.0 - 1.2%	2.7 - 4.2%	1.0 - 1.6%
Expected dividend yield	None	None	None	None

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

(7) Product Development and Licensing Agreements

Our revenue from product development and licensing agreements was received pursuant to contracts with different organizations. Total revenue recognized by us in connection with these contracts for the six months ended June 30, 2004 and for the years ended December 31, 2003, 2002 and 2001 were approximately \$2,248,800, \$1,803,900, \$6,412,400 and \$2,999,800, respectively. A summary of these contracts follows:

(A) *GlaxoSmithKline plc*

During 1997, AVANT entered into an agreement with GlaxoSmithKline plc (“Glaxo”) to collaborate on the development and commercialization of our oral rotavirus vaccine. Under the terms of the agreement, Glaxo received an exclusive worldwide license to commercialize AVANT’s rotavirus vaccine. We were responsible for continuing the Phase II clinical efficacy study of the rotavirus vaccine, which was completed in August 1998. Glaxo made an initial license payment of \$250,000 in 1997 upon execution of the agreement. In June 1999, we received a milestone payment of \$500,000 from Glaxo for the successful completion of the Phase II clinical efficacy study and the establishment of a commercially viable process for manufacture of the vaccine. Glaxo has assumed responsibility for all subsequent clinical trials and all other development activities. Glaxo initiated global Phase III clinical trials of Rotarix® in the third quarter of 2003, and AVANT recognized a \$1.0 million milestone. In July 2004, the Mexican Board of Health approved the marketing of Rotarix® in Mexico. 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 \$100,000 in the six months ended June 2004 and 2003, respectively. The term of this agreement is through the expiration of the last of the patents covered by the agreement, although Glaxo may terminate the agreement upon 90 days prior written notice. Glaxo has agreed to make further payments, which could total up to \$7.5 million, upon the achievement of specified milestones. In addition, we will be entitled to royalties based on net sales of Rotarix®.

(B) *Pfizer Inc*

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

(C) *DynPort Vaccine Company LLC*

In October 2001, we granted DynPort Vaccine Company LLC (DVC) a license for exclusive rights to use certain components of AVANT’s anthrax vaccine technology. In October 2001, in connection with the execution of the agreement, AVANT received a \$200,000 materials transfer fee. Also in October 2002, DVC announced the initiation of a Phase I clinical trial of a new injectable recombinant anthrax vaccine in approximately 70 volunteers. The vaccine candidate consists of a highly purified protein—Protective Antigen—derived from the anthrax bacterium using recombinant technology and production processes licensed from AVANT. Under the agreement, AVANT is also entitled to annual \$50,000 license maintenance payments, with respect to which AVANT has received \$100,000, and milestone payments of up to \$700,000 in the aggregate, \$100,000 of which AVANT received upon initiation of a Phase I clinical trial in 2002. AVANT is also entitled to specified royalties on eventual product sales. The term of this agreement is through the expiration of the last of the patents covered by the agreement, although DVC may terminate the agreement upon 90 days prior written notice. DVC, a privately-held company, is chartered with providing an integrated approach for the advanced development of specific vaccines and other products to protect against the threat of biological warfare agents. DVC has a 10-year contract with the U.S. Department of Defense for the development of vaccines against certain acute infectious and contagious diseases, initiated under the 1997 Joint Vaccine Acquisition Program. AVANT has no obligation to incur any research and development costs in connection with this agreement.

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

(D) *AdProTech*

In March 2004, we granted a license to AdProTech, Ltd for non-exclusive rights to use certain components of AVANT’s intellectual property surrounding complement inhibition. In April 2004, AVANT received an initial license payment of \$1 million from AdProTech. As we have no continuing

or obligation under this license agreement, we 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.

(8) Direct Equity Placement

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

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, CholeraGardeÔ (Peru-15), Ty800, CETi-1, Therapore® and of other products; (4) the cost, timing, scope and results of ongoing safety and efficacy trials of TP10, CholeraGardeÔ (Peru-15), Ty800, CETi-1, Therapore® and other preclinical and clinical testing; (5) the ability to successfully complete product research and further development, including animal, pre-clinical and clinical studies of TP10, CholeraGardeÔ (Peru-15), Ty800, CETi-1, Therapore® and other products; (6) the ability of the Company to manage multiple late stage clinical trials for a variety of product candidates; (7) royalty revenues from product sales of Rotarix®, Megan®Vac 1, Megan®Egg and other future products; (8) changes in existing and potential relationships with corporate collaborators; (9) the cost, delivery and quality of clinical and commercial grade materials supplied by contract manufacturers; (10) the timing, cost and uncertainty of obtaining regulatory approvals to use TP10, for among other purposes, for adults undergoing cardiac surgery, to use CholeraGardeÔ (Peru-15) and Ty800, among other purposes, to protect travelers and people in endemic regions from diarrhea causing diseases, to use CETi-1, among other purposes, to raise serum HDL cholesterol levels and for other products; (11) the ability to obtain substantial additional funding; (12) the ability to develop and commercialize products before competitors; (13) the ability to retain certain members of management; and (14) other factors detailed from time to time in filings with the Securities and Exchange Commission. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences. These forward-looking statements were based on information, plans and estimates at the date of this report, and we do not promise to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.*

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

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

CRITICAL ACCOUNTING POLICIES

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

OVERVIEW

AVANT's focus is unlocking the power of the immune system to prevent and treat disease. We have assembled a broad portfolio of technologies and intellectual property that give us 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 our products are in clinical development. The development of immunotherapeutic vaccines like CETi-1 and the marriage of innovative vector delivery technologies with the unique VitriLife® manufacturing process represent the potential for a new generation of vaccines. Our goal is to become a leading developer of such innovative vaccines and immunotherapeutics that address health care needs on a global basis.

We have actively developed and acquired innovative technologies – especially novel approaches to vaccine creation. Today our broad intellectual property position allows us to respond quickly and leverage our expertise into many different areas as opportunities and needs arise. For example, our vaccine technology for providing rapid protection against bacterial illnesses may prove useful for improving and expanding America's vaccine arsenal against microbial agents used in war or terrorist attacks.

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

ACQUISITIONS

Universal Preservation Technologies, Inc.: In January 2003, AVANT completed the acquisition of certain technology and intellectual property of Universal Preservation Technologies, Inc. (UPT), a privately held company, 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 in connection with those patents relating to orally administered vaccines, and non-exclusive rights in certain other fields.

Through this transaction, AVANT has gained exclusive rights to the VitriLife[®] process for use in AVANT's oral vaccines and certain other non-injectable applications. VitriLife[®] is a patented drying method for the industrial-scale preservation of biological solutions and suspensions, such as proteins, enzymes, viruses, bacteria and other cells, which has the potential to cut production costs and improve product stability at room temperature or higher. We have determined that this technology has alternative future uses and will be incorporated into a number of AVANT's bacterial vaccine programs. AVANT paid an aggregate of \$2,000,000 in consideration in the transaction, recorded this value to acquired intangible assets, and is amortizing these assets over their estimated lives of ten years.

Megan Health, Inc.: On December 1, 2000, AVANT acquired all of the outstanding capital stock of Megan Health, Inc. ("Megan"), a company engaged in the discovery and development of human and animal vaccines using patented gene modification technologies. In connection with the acquisition, we recorded a charge of \$9,012,300 for acquired in-process research and development ("IPR&D"), which represented purchased in-process technology which had not yet reached technological feasibility and had no alternative future use. As of June 30, 2004, none of the acquired research and development projects had reached technical 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, we recorded a charge of \$44,630,000 for acquired IPR&D, which represented purchased in-process technology which had not yet reached technological feasibility and had no alternative future use. As of June 30, 2004, none of the acquired research and development projects had reached technical feasibility.

RESEARCH AND DEVELOPMENT ACTIVITIES

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

The expenditures that will be necessary to execute AVANT's business plan are subject to numerous uncertainties. Completion of clinical trials may take several years or more, but the length of time

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

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

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

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

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

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

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

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

As a result of the uncertainties discussed above, among others, AVANT is unable to estimate the duration and completion costs of its research and development projects or when, if ever, and to what extent it will receive cash inflows from the commercialization and sale of a product. AVANT's inability to complete its research and development projects in a timely manner or its failure to enter into collaborative agreements, when appropriate, could significantly increase its capital requirements and could adversely impact its liquidity. These uncertainties could force AVANT to seek additional, external sources of financing from time to time in order to continue with its business strategy. AVANT's inability to raise additional capital, or to do so on terms reasonably acceptable to it, would jeopardize the future success of its business. The amount incurred for each material research program since the beginning of 2001, is set forth below under "Program Developments." During the past five years through the end of 2003, AVANT incurred an aggregate of \$65.0 million in research and development costs. During the six months ended June 30, 2004, AVANT incurred an aggregate of \$6.8 million in research and development costs. The following table indicates the amount incurred for each of AVANT's material research programs and for other identified research and development activities during the three years ended December 31, 2003, 2002, and 2001 and the six-month periods ended June 30, 2004 and 2003. The amounts disclosed in the following table and in "Program Developments" below reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program. Prior to January 1, 2000, AVANT did not track research and development costs by program and, therefore we are unable to disclose spending by program prior to that date.

	Six Months Ended June 30,		Year Ended December 31,		
	2004	2003	2003	2002	2001
<i>Cholesterol Management Vaccine:</i>					
CETi-1	\$ 408,200	\$ 2,004,000	\$ 3,404,000	\$ 3,176,800	\$ 2,387,700
<i>Bacterial Vaccines:</i>					
CholeraGarde [®]	53,200	657,600	695,800	5,959,100	2,369,200
Ty800	457,600	203,000	186,300	2,203,600	1,863,500
Other	82,500	117,800	137,500	204,400	—
<i>BioDefense Vaccines:</i>	1,921,200	1,604,100	3,524,500	239,900	—
<i>Food Safety & Animal Health Vaccines:</i>	8,300	36,500	49,400	450,600	984,900
<i>Viral Vaccines:</i>					
Rotavirus vaccine	100,000	250,000	200,000	400,000	334,100
Other	180,300	36,000	72,400	346,800	264,600
<i>Complement Inhibitors:</i>					
TP10/TP20	3,464,500	456,900	1,648,700	1,714,800	12,930,500
<i>Other Programs:</i>	145,200	—	102,700	—	—
<i>Discontinued Programs:</i>	—	—	—	12,500	446,000
Total R&D Expense	\$ 6,821,000	\$ 5,365,900	\$ 10,021,300	\$ 14,708,500	\$ 21,580,500

PROGRAM DEVELOPMENTS

Cholesterol Management Vaccine: We are developing an immunotherapeutic vaccine against endogenous cholesteryl ester transfer protein ("CETP"), which may be useful in reducing risks associated with atherosclerosis. CETP is a key intermediary in the balance of HDL (high-density lipoprotein) and LDL (low-density lipoprotein). We are developing this vaccine, CETi-1, to stimulate an immune response against CETP, which we believe may improve the ratio of HDL to LDL cholesterol and reduce the progression of atherosclerosis. We have conducted preliminary studies of rabbits, which have demonstrated the ability of CETi-1 vaccine to elevate HDL and reduce the development of blood vessel lesions.

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

These data were helpful in moving the program forward to a placebo controlled Phase II study, which was initiated in August 2001, in approximately 200 patients with low levels of HDL cholesterol. The objectives of the study were to evaluate the safety, immunogenicity and dose-response relationship of the CETi-1 product in patients who receive an initial immunization followed by boosters. The primary endpoint was the change in HDL cholesterol measured after the six-month booster. In October 2003, AVANT completed the CETi-1 vaccine Phase II efficacy study. The results of the study demonstrated proof-of-concept in humans confirming that blocking cholesterol transfer could raise HDL levels. In addition, the CETi-1 vaccine worked as designed to elicit anti-CETP antibodies in a high percentage of patients treated, approximately 90%. We are currently evaluating a number of new adjuvants and delivery technologies for our CETP vaccine in animal models and expect to choose the approach eliciting the most robust antibody response by year-end. During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$10.9 million in research, development and clinical costs associated with the CETi program. During the six months ended June 30, 2004, AVANT incurred approximately \$408,200 in research, development and clinical costs associated with the CETi program. We plan to seek a corporate partner to complete development and to commercialize the CETi vaccine.

Bacterial Vaccines: Modern biotechnology offers great potential for bettering health conditions worldwide. New vaccine technologies, in particular, can provide avenues to disease prevention and treatment with notable advantages over drugs in terms of patient compliance and cost. They also offer strategies to solve global health problems, to protect both civilians and military from biowarfare threats, and to increase the safety of our food supply. Our goal is to become a leading developer of innovative vaccines that address health care needs on a global basis. In this regard, we acquired VitriLife®, a technology with the potential to reduce manufacturing costs and improve product stability, eliminating the need for vaccine refrigeration. With this technology and our *Cholera*- and *Salmonella*-vectored delivery technologies, named VibrioVec™ and SalmoVec™, we can now develop a new generation of vaccines that have an ideal product profile: safe, effective, oral, single-dose, rapidly protective and requiring no refrigeration.

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

In 2003, AVANT terminated its manufacturing contract with Bio Sidus, S.A., of Buenos Aires, Argentina, for the manufacture of its CholeraGarde® vaccine. The two companies resolved their contractual issues and settled all claims during the fourth quarter of 2003. Clinical material for the IVI

trials in Bangladesh previously has been manufactured by the Walter Reed Army Institute of Research (WRAIR), and AVANT and WRAIR have entered into a manufacturing agreement to supply CholeraGarde®.

During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$9.2 million in research, development and clinical costs on its CholeraGarde® program. During the six months ended June 30, 2004, AVANT incurred approximately \$53,200 in research, development and clinical costs on its CholeraGarde® program.

In addition, the National Institute of Allergy and Infectious Disease (NIAID) of the National Institutes of Health (NIH) and AVANT have agreed for the NIAID to conduct a Phase I in-patient dose-ranging clinical trial aimed at demonstrating the safety and immunogenicity of the Ty800 typhoid fever vaccine. The trial is planned for a NIAID-funded clinical site using NIAID-funded clinical material. The NIAID trial seeks to confirm the safety and immunogenicity of the Ty800 oral vaccine observed in an earlier physician-sponsored Ty800 vaccine study. During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$4.3 million in research, development and clinical costs on its Ty800 program. During the six months ended June 30, 2004, AVANT incurred approximately \$457,600 in research, development and clinical costs on its Ty800 program.

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

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

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

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

Further, in January 2003, AVANT was awarded a subcontract to develop for the U.S. Department of Defense an oral combination vaccine against anthrax and plague using AVANT's proprietary vaccine technologies. AVANT executed this initial subcontract with DVC and will be reimbursed on a time and materials basis for vaccine development research work performed by AVANT in the amount of \$2.5 million. In June 2003, AVANT was awarded a second subcontract for approximately \$1.3 million to support preclinical animal testing of vaccine constructs being developed by AVANT for the oral combination vaccine against anthrax and plague. In April 2004, AVANT was awarded a third subcontract for approximately \$3 million to support the human clinical testing of a plague vaccine candidate being developed by AVANT for use in the oral combination vaccine. Payments under the subcontract agreement are made on a time and materials basis and receipt of the full amount is conditioned upon the project being fully funded through completion and AVANT performing and continuing to demonstrate that it has the capability to perform the funded work.

In August 2003, the Company announced that it had reached agreement with MassDevelopment, an economic development entity for the Commonwealth of Massachusetts, for AVANT to occupy and build-out a pilot-manufacturing facility in Fall River, Massachusetts. AVANT is establishing this 11,800 square foot facility to support the clinical development of its portfolio of bacterial vaccines, including vaccines for biodefense, as well as the continued development and product application of VitriLife®.

During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$3.8 million in research and development costs on its biodefense vaccine program. During the six months ended June 30, 2004, AVANT incurred approximately \$1.9 million in research and development costs on its biodefense vaccine program.

Food Safety and Animal Health Vaccines: AVANT has partnered with Pfizer, who will apply AVANT's vaccine technologies to animal health and human food safety markets. The Pfizer research program achieved an important milestone in late 2002, which resulted in a payment of \$500,000 to AVANT. During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$1.5 million in research and development costs on its food safety and animal health vaccines program. During the six months ended June 30, 2004, AVANT incurred approximately \$8,300 in research and development costs on its food safety and animal health vaccines program.

Rotavirus Vaccine: Rotavirus is a major cause of diarrhea and vomiting in infants and children. No vaccine against rotavirus is currently on the market. In 1997, we licensed our oral rotavirus vaccine to Glaxo. In 1999, after our Phase II study demonstrated 89% protection in a study involving 215 infants, Glaxo paid us an additional license fee and assumed full responsibility for funding and performing all remaining clinical development. Substantially all of the ongoing development is being conducted and funded by Glaxo. During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$1.1 million in licensing fees and \$79,000 in research and development costs. During the six months ended June 30, 2004, AVANT incurred approximately \$100,000 in licensing fees associated with the rotavirus program. Prior to January 1, 2000, AVANT did not track research and development costs by program and, therefore, we are unable to disclose spending by program prior to that date. Glaxo has completed Phase I/II bridging studies in over 6,000 infants in Europe, Latin America and Asia using its two-dose oral rotavirus vaccine, called Rotarix®. Glaxo initiated global Phase III clinical trials of Rotarix® in the third quarter of 2003, and AVANT recognized a \$1.0 million milestone. In July 2004, the Mexican Board of Health approved the marketing of Rotarix® in Mexico. Assuming product development and commercialization continues satisfactorily, we may receive additional milestone payments totaling \$7.5 million upon the achievement of specified milestones. In addition, we will be entitled to royalties based on net sales of Rotarix®.

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

pursuant to which Novartis paid a net termination fee of \$1.9 million and returned to AVANT all pre-clinical and clinical TP10 material.

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

The important treatment benefits seen in the male population were directly related to mortality and the benefit seen was impressive. This further analysis of the study data showed continued promise for this molecule and AVANT has announced its renewed commitment to its development. AVANT is conducting 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, will conclude around year-end 2004, and will be conducted at approximately 25 sites throughout the United States. The goals of the trial are to clarify the effect that TP10 has for women undergoing cardiac surgery, as well as augment the safety data for that patient population to allow for the design of a subsequent registration-directed trial. In addition, we are working closely with our partner, Lonza Biologics plc, to complete process development and scale-up efforts this year in preparation for the production of Phase III clinical materials and the start of that trial by year-end 2005.

During the period January 1, 2000 through December 31, 2003, AVANT incurred approximately \$22.8 million in research, development and clinical costs. During the six months ended June 30, 2004, AVANT incurred approximately \$3.5 million in research, development and clinical costs associated with its complement programs. With the termination of the Novartis agreement in 2002, AVANT can now offer a worldwide license for all fields, and may seek partnering arrangements to capture the value inherent in this program and its strong intellectual property portfolio.

TECHNOLOGY LICENSING

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

DynPort License: In October 2001, AVANT granted a license to DynPort Vaccine Company LLC (DVC) for exclusive rights to use certain components of AVANT's vaccine technology. Financial terms of the agreement with DVC include license fees, milestone payments and royalties. DVC, a private company, is chartered with providing an integrated approach for the advanced development of specific vaccines and other products to protect against the threat of biological warfare agents. DVC has a 10-year contract with the U.S. Department of Defense for the development of vaccines against certain acute infectious diseases and contagious diseases, initiated under the 1997 Joint Vaccine Acquisition Program. We see this licensing opportunity as a way to further leverage our vaccine technology.

RESULTS OF OPERATIONS

Three-Month Period Ended June 30, 2004 as Compared
With the Three-Month Period Ended June 30, 2003

AVANT reported consolidated net loss of \$3,898,800, or \$.05 per share, for the second quarter ended June 30, 2004, compared with a net loss of \$3,183,300, or \$.05 per share, for the second quarter

ended June 30, 2003. The weighted average common shares outstanding used to calculate net loss per common share was 74,091,600 in 2004 and 60,468,700 in 2003.

Revenue: Total revenue decreased \$185,400, or 17.2%, to \$893,000 for the second quarter of 2004 compared to \$1,078,400 for the second quarter of 2003.

Product development and licensing revenue decreased \$62,600, or 33.5%, to \$124,400 in 2004 from \$187,000 in 2003. Product development and licensing revenue consisted primarily of the amortization of nonrefundable license fees from Pfizer. The remaining Pfizer license fees totaling \$207,400 will be fully amortized by November 2004.

In January and June 2003 and April 2004, AVANT was awarded Department of Defense subcontracts from its partner, DVC, that supports the development of an oral, combination vaccine against both anthrax and plague using our vectored vaccine technology. AVANT will be reimbursed by DVC on a time and materials basis for vaccine development research work performed by AVANT in the amount of approximately \$6.8 million. Under these agreements and several SBIR grants, AVANT recognized \$714,700 and \$849,300 in government contract and grant revenue during the second quarters of 2004 and 2003, respectively, for work performed.

In 2002, we transferred the marketing and distribution of the Megan poultry product line to our 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 second quarter of 2004 and 2003 totaled \$53,900 and \$42,100, respectively. Megan®Vac 1 and Megan®Egg are vaccines for use in chickens for protection against multiple strains of *Salmonella* bacteria, which we acquired in connection with our acquisition of Megan.

Operating Expense: Total operating expense increased \$612,400, or 14.3%, to \$4,886,300 for the second quarter of 2004 compared to \$4,273,900 for the second quarter of 2003. The increase in total operating expense in 2004 primarily results from an increase in research and development expense in the second quarter of 2004 due to increased clinical trials costs and contract manufacturing costs.

Research and development expense increased \$694,400, or 26%, to \$3,367,800 in 2004 from \$2,673,400 in 2003. The increase in 2004 compared to 2003 is primarily due to an increase in clinical trials costs of \$294,800 and contract manufacturing costs of \$497,300, both incurred on the TP10 program. The increase in research and development expense further resulted from increases in laboratory supplies and services expenses of \$55,100, offset in part by declines in personnel and related expenses of \$55,700, consultancy costs of \$47,300, facility-related costs of \$97,400 and license fees of \$71,900.

General and administrative expense decreased \$82,000, or 6.1%, to \$1,269,700 in 2004 compared to \$1,351,700 in 2003 and is primarily attributed to decreases in consultancy costs of \$30,300, facility-related costs of \$18,200 and legal costs of \$64,200, offset in part by an increase in personnel and related costs of \$66,000.

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

Investment Income, Net: Interest income increased \$82,300 to \$94,500 for the second quarter of 2004 compared to \$12,200 for the second quarter of 2003. The increase is primarily due to higher cash balances during the second quarter of 2004 compared to the second quarter of 2003. During the second three months of 2004 and 2003, the average month-end cash balances were \$40,183,500 and \$17,777,100, respectively. The effective interest rates during the second three months of 2004 and 2003 were 0.95% and 1.20%, respectively.

Six-Month Period Ended June 30, 2004 as Compared
with the Six-Month Period Ended June 30, 2003

AVANT reported a consolidated net loss of \$5,808,200, or \$.08 per share, for the six months ended June 30, 2004, compared with a net loss of \$6,545,500, or \$.11 per share, for the six months ended June 30, 2003. The weighted average common shares outstanding used to calculate net loss per common share was 71,655,100 in 2004 and 60,468,700 in 2003.

Revenue: Total revenue increased \$2,163,600 to \$3,923,700 for the first six months of 2004 compared to \$1,760,100 for the first six months of 2003.

Product development and licensing revenue increased \$1,915,000 to \$2,248,800 for the first six months of 2004 from \$333,800 for the first six months of 2003. The increase is primarily due to the one-time recognition of \$1 million in revenue from DVC for rPA clinical materials and a license fee of \$1 million from AdProTech, Ltd.

AVANT has received a number of subcontracts from its partner, DVC, to develop anthrax and plague vaccines for the U.S. Department of Defense. AVANT will be reimbursed by DVC on a time and materials basis for vaccine development research work performed by AVANT. Under these agreements and several SBIR grants, AVANT recognized \$1,594,600 and \$1,348,900 in government contract and grant revenue during the first six months of 2004 and 2003, respectively. AVANT expects the amount of research work to be performed for DVC during the second half of 2004 to approximate the amount of research work performed during the first six months of 2004 and 2003.

As of September 1, 2002, we 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 six months of 2004 and 2003 totaled \$80,300 and \$77,400, respectively.

Operating Expense: Total operating expense increased \$1,440,500, or 17.1%, to \$9,880,400 for the first six months of 2004 compared to \$8,439,900 for the first six months of 2003. The increase in total operating expense for the first six months of 2004 compared to the first six months of 2003 is primarily due to an increase in costs associated with conducting clinical trials and contract manufacturing to support our TP10 program.

Research and development expense increased \$1,455,100, or 27.1%, to \$6,821,000 for the first six months of 2004 compared to \$5,365,900 for the first six months of 2003. The increase in 2004 compared to 2003 is primarily due to increases in contract manufacturing costs of \$923,500, clinical trial costs of \$779,800 both associated with the TP10 program, and laboratory supplies and services expenses of \$103,400. These increases were offset in part by declines in personnel and related expenses of \$20,100, consultancy costs of \$89,300, license fees of \$343,400, and facility related expenses of \$37,600. AVANT expects research and development expense to increase further in the third and fourth quarters of 2004 as the TP10 Phase II female clinical trial is fully enrolled and as AVANT's contract manufacturer completes process development and scale-up work in preparation for the production of Phase III clinical materials in 2005.

General and administrative expense decreased \$14,600 to \$2,561,800 for the first six months of 2004 compared to \$2,576,400 for the first six months of 2003. The decrease in 2004 is primarily attributed to decreases in facility related costs, legal, consulting and insurance expenses, offset partly by increased personnel and related expenses. AVANT expects general and administrative expense during the second half of 2004 to approximate the expense incurred during the first six months of 2004 and 2003.

Amortization expense of acquired intangible assets was \$497,600 in the first six months of 2004 and 2003.

Investment Income, Net: Net investment income increased \$14,200, or 10.6%, to \$148,500 for the first six months of 2004 compared to \$134,300 for the first six months of 2003. The increase is primarily due to higher average cash balances during the first six months of 2004 compared to the first six months of

2003. During the first six months of 2004 and 2003, the average month-end cash balances were \$37,156,200 and \$19,352,600, respectively. The effective interest rates during the first six months of 2004 and 2003 were 0.95% and 1.24%, respectively.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations primarily through license fees, research and development funding from our collaborative partners, funding from government contracts and grants, product sales and product royalties, the private and public placement of our equity securities and debt financings.

At June 30, 2004, our principal sources of liquidity consisted of cash and cash equivalents of \$39,370,700. Our cash and cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of time deposits and investments in money market mutual funds with commercial banks and financial institutions, short-term commercial paper, and U.S. Government and other investment grade debt securities. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances.

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our office 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 our collaborative partners and from government entities. In general, our 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 we may receive. The timing of any new collaboration agreements, government contracts or grants and any payments under these agreements, contracts or grants cannot be easily predicted and may vary significantly from quarter to quarter.

Net cash used in operating activities decreased to \$3,800,600 for the first six months of 2004 compared to \$5,735,000 for the first six months of 2003. The decrease is primarily attributed to the decrease in net loss incurred in 2004 compared to 2003, a decrease in accounts receivable, including a \$1,000,000 up-front payment received for a licensing agreement with AdProTech, and an increase in accounts payable and accrued expenses, offset partly by a decrease in deferred revenue, including the recognition of \$1 million from DVC. We expect that our cash used in operations will continue to increase as we continue to develop our products in clinical trials, contract for the manufacture of clinical materials and advance new products into preclinical development. The increase in cash used would be partially offset by anticipated payments made under our government contracts and grants and anticipated product royalty payments.

Net cash used in investing activities decreased to \$401,000 for the first six months of 2004 compared to \$2,263,700 for the first six months of 2003. The decrease is primarily due to \$2 million of cash paid in 2003 for certain assets of Universal Preservation Technologies, Inc., offset in part by increased investment in property and equipment in 2004 compared to 2003. We expect we will continue to use cash in our investing activities as we expand our infrastructure and complete the build-out of our Fall River pilot manufacturing facility.

Net cash provided by financing activities was \$23,321,300 for the first six months of 2004 compared to net cash used in financing activities of \$87,900 for the first six months of 2003. The increase is due primarily to the completion of a direct equity placement in 2004 and an increase in proceeds from the exercise of stock options and warrants.

AGGREGATE CONTRACTUAL OBLIGATIONS

As of June 30, 2004, AVANT had future payments required under contractual obligations and other commitments approximately as follows:

<u>Total</u>	<u>Less than One Year</u>	<u>1-3 Years</u>	<u>3-5 Years</u>	<u>4-5 Years</u>
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Operating lease obligations	\$ 9,314,500	\$ 2,331,800	\$ 6,097,000	\$ 604,200	\$ 281,500
Licensing obligations	920,000	310,000	355,000	170,000	85,000
Total future obligations	<u>\$ 10,234,500</u>	<u>\$ 2,641,800</u>	<u>\$ 6,452,000</u>	<u>\$ 774,200</u>	<u>\$ 366,500</u>

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

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

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

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, within the 90 days prior to the date of this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating our disclosure controls and procedures, we and our management recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that they believe that, as of the date of completion of the evaluation, our disclosure controls and procedures were reasonably effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. We will continue to review and document our disclosure controls and

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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.

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PART II — OTHER INFORMATION

Item 4. Submission of Matters to a Vote of Security Holders

On May 13, 2004, AVANT held its Annual Meeting of Stockholders at which the stockholders elected six directors to our Board of Directors.

At the Annual Meeting of Stockholders, the following votes were tabulated for the two proposals before AVANT's Stockholders:

PROPOSAL I

To approve the 2004 Employee Stock Purchase Plan.

<u>For</u>	<u>Against</u>	<u>Abstain</u>
15,187,595	1,192,576	184,328

PROPOSAL II

Election of Directors:

	Number of Shares/Votes	
	For	Authority Withheld
J. Barrie Ward, Ph.D.	58,170,389	1,949,069
Una S. Ryan, Ph.D.	59,559,683	559,775
Harry H. Penner, Jr.	59,224,982	894,476
Peter A. Sears	59,097,538	1,021,920
Karen Shoos Lipton	59,521,366	598,092
Larry Ellberger	59,203,452	916,006

The number of shares issued, outstanding and eligible to vote as of the record date of March 19, 2004 was 74,291,400. A quorum was present with 60,119,458 shares represented by proxies or 80.92% of the eligible voting shares.

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 April 21, 2004 regarding a press release announcing that AVANT had reported its financial results for the first quarter ended March 31, 2004.

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: August 4, 2004

/s/ Una S. Ryan

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

Dated: August 4, 2004

/s/ Avery W. Catlin

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

EXHIBIT INDEX

Exhibit No.	Description
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

CERTIFICATION

I, Una S. Ryan, certify that:

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

Date: August 4, 2004

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

CERTIFICATION

I, Avery W. Catlin, certify that:

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

Date: August 4, 2004

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

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

Date: August 4, 2004

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

Date: August 4, 2004

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