# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# **FORM 10-Q**

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

For the quarterly period ended September 30, 2006

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 x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o

Accelerated filer x

Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of November 6, 2006, 74,182,548 shares of common stock, \$.001 par value per share, were outstanding.

# AVANT IMMUNOTHERAPEUTICS, INC.

FORM 10-Q Quarter Ended September 30, 2006 Table of Contents

# **Part I—Financial Information**

Item 1. Financial Statments

Unaudited, Consolidated Balance Sheets at September 30, 2006 and December 31, 2005

Unaudited, Consolidated Statements of Operations for the Three Months Ended September 30, 2006 and 2005

Unaudited, Consolidated Statements of Operations for the Nine Months Ended September 30, 2006 and 2005

Unaudited, Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2006 and 2005

Notes to Unaudited, Consolidated Financial Statements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Item 4. Controls and Procedures

# Part II — Other Information

Item 1A. Risk Factors

Item 6. Exhibits

<u>Signatures</u>

Certifications

2

# PART I—FINANCIAL INFORMATION

# Item 1. Financial Statements

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

	September 30, 2006			
ASSETS				
Current Assets:				
Cash and Cash Equivalents	\$	46,681,330	\$	23,419,434
Accounts Receivable		554,358		418,380
Prepaid Expenses and Other Current Assets		927,199		767,082
Total Current Assets		48,162,887		24,604,896
Property and Equipment, Net		10,534,372		5,743,663
Intangible and Other Assets		4,320,740		5,067,073
Goodwill		1,036,285		1,036,285
Total Assets	\$	64,054,284	\$	36,451,917
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts Payable	\$	831,138	\$	1,140,578
Accrued Expenses		2,624,701		2,334,708
Current Portion of Deferred Revenue		4,553,082		
Current Portion of Other Long-Term Liabilities		222,542		217,457
Total Current Liabilities		8,231,463		3,692,743
Deferred Revenue		45,033,615		10,000,000
		3,089,611		10,000,000 1,870,051
Other Long-Term Liabilities		5,009,011		1,0/0,051
Stockholders' Equity:				
Convertible Preferred Stock, 4,513,102 Shares Authorized; None Issued and Outstanding				_
Common Stock, \$.001 Par Value; 100,000,000 Shares Authorized; 74,402,867 Issued and 74,182,548 Outstanding at September 30, 2006 and 74,387,087 Issued and 74,166,768 Outstanding at December 31,				
2005		74,403		74,387
Additional Paid-In Capital		257,887,168		258,139,855
Deferred Compensation				(1,225,000)
Less: 220,319 Common Treasury Shares at Cost		(227,646)		(227,646)
Accumulated Deficit		(250,034,331)		(235,872,473)
Total Stockholders' Equity		7,699,595		20,889,123
Total Liabilities and Stockholders' Equity	\$	64,054,284	\$	36,451,917

See accompanying notes to unaudited consolidated financial statements

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

),	
	September 30, 2005
75	\$ 78,692
19	767,630
05	
	0.46.000
99	846,322
20	3,591,334
99	1,670,306
78	248,778
97	5,510,418
98)	(4,664,096)
31	149,662
67)	(4,514,434)
_	
67)	\$ (4,514,434)
<u> </u>	$\varphi$ (4,514,454)
07)	\$ (0.06)
47	74,145,814
8 3 5	

See accompanying notes to unaudited consolidated financial statements

4

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

	Nine Mor	ths Ended
	September 30, 2006	September 30, 2005
REVENUE:		
Product Development and Licensing Agreements	\$ 2,672,895	\$ 209,209
Government Contracts and Grants	1,241,149	2,156,680
Product Royalties	636,921	88,146
Total Revenue	4,550,965	2,454,035
OPERATING EXPENSE:		
Research and Development	13,228,926	11,052,944
General and Administrative	5,924,505	5,242,185
Amortization of Acquired Intangible Assets	746,334	746,334
Total Operating Expense	19,899,765	17,041,463
Operating Loss	(15,348,800)	(14,587,428)
Investment and Other Income, Net	1,558,943	470,556
Loss before Provision for Income Taxes	(13,789,857)	(14,116,872)
Provision for Income Taxes	372,000	
Net Loss	\$ (14,161,857)	\$ (14,116,872)
Basic and Diluted Net Loss Per Common Share	\$ (0.19)	\$ (0.19)
Weighted Average Common Shares Outstanding	74,176,593	74,136,931

5

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

		Nine Months Ended		
	_	September 30, 2006	S	September 30, 2005
Cash Flows from Operating Activities:	_	2000		2005
Net Loss	\$	(14,161,857)	\$	(14,116,872)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:				
Depreciation and Amortization		1,505,578		1,142,620
Stock-Based Compensation Expense		953,297		363,000
Changes in Operating Assets and Liabilities:				
Accounts Receivable		(135,978)		1,586,930
Prepaid and Other Current Assets		(160,117)		(182,798)
Accounts Payable and Accrued Expenses		(19,447)		(1,884,293)
Deferred Revenue		39,586,697		5,000,793
Other Long-Term Liabilities		1,405,351		
Net Cash Provided by (Used in) Operating Activities		28,973,524		(8,090,620)
Cash Flows from Investing Activities:				
Acquisition of Property and Equipment		(5,549,954)		(1,351,233)
Other Non-Current Assets		_		1,000
Net Cash Used in Investing Activities		(5,549,954)		(1,350,233)
	_			
Cash Flows from Financing Activities:				
Proceeds from Stock Issuance		13,897		5,438
Proceeds from Exercise of Stock Options and Warrants		5,135		28,928
Payment of Long-Term Liabilities		(180,706)		(136,232)
			_	
Net Cash Used in Financing Activities		(161,674)		(101,866)
Net Increase (Decrease) in Cash and Cash Equivalents		23,261,896		(9,542,719)
······································		-, - ,		(-)- ) -)
Cash and Cash Equivalents at Beginning of Period		23,419,434		31,741,494
		_, _, _		_ , , _
Cash and Cash Equivalents at End of Period	\$	46,681,330	\$	22,198,775
	÷	-,	<u> </u>	, , -
Supplemental Disclosure of Cash Flow Information				
Cash paid for interest	\$	87,255	\$	89.894
Cush pute for interest	ψ	07,200	Ψ	05,054

See accompanying notes to unaudited consolidated financial statements

6

## AVANT IMMUNOTHERAPEUTICS, INC. Notes to Unaudited Consolidated Financial Statements September 30, 2006

# (1) <u>Nature of Business</u>

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 infectious diseases. The portfolio includes a pipeline of preventative, single-dose oral vaccines aimed at protecting travelers and people in regions where infectious diseases are endemic. The portfolio also includes immunotherapeutics for cardiovascular diseases which are available for partnering, including a treatment to reduce complement-mediated tissue damage associated with cardiac by-pass surgery and a proprietary vaccine candidate for cholesterol management. In addition, the Company is developing the VitriLifeÒ preservation and lyophilization technologies 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, governmental and non-governmental partnerships. One successful collaboration resulted in the development and marketing of an oral human rotavirus vaccine. Current collaborations encompass the development of vaccines to combat threats of biological warfare and vaccines addressed to global health, human food safety and animal health. The unaudited consolidated financial statements include the accounts of AVANT 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, 2006 and 2005 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, 2006, results of operations for the three months and nine months ended September 30, 2006 and 2005, and cash flows for the nine-month periods ended September 30, 2006 and 2005. The results of operations for the nine-month period ended September 30, 2006 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 in the United States of America 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, 2005, are adequate to make the information presented not misleading. The accompanying December 31, 2005 Consolidated Balance Sheet was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

#### (3) <u>Recent Accounting Pronouncements</u>

**SFAS 157:** In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements, the Board having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements. However, for some entities, the application of SFAS 157 will change current practice. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We have not yet determined the effect if any that adopting SFAS 157 will have on the Company's financial statements.

**SAB 108:** In September 2006, the Securities and Exchange Commission ("SEC") released Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ("SAB 108"). SAB 108 requires that public companies utilize a "dual-approach" to assess the quantitative effects of financial misstatements. This dual approach includes both an income statement focused assessment and a balance sheet assessment. The guidance in SAB 108 must be applied to annual financial statements for fiscal years beginning after November 15, 2006. The Company does not expect that the adoption of SAB 108 will have a material effect on the Company's consolidated financial position or results of operations.

**FIN 48:** In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ("FIN 48"). FIN 48 addresses the recognition and measurement of uncertain income tax positions using a "more-likely-than-not" threshold and introduces a number of new disclosure requirements. The new guidance is effective for fiscal years beginning after December 15, 2006. Because of the Company's tax loss position, the adoption of FIN 48 will not have a material impact on AVANT's near-term financial position and results of operations.

# (4) <u>Paul Royalty Fund</u>

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 RotarixÒ. RotarixÒ is licensed to GlaxoSmithKline plc ("Glaxo"). The terms of the agreement with PRF include an upfront unconditional payment from PRF totaling \$10 million received in 2005 and the following milestone payments: (i) \$40 million for product launch in the European Union received March 17, 2006, 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 RotarixÒ. If worldwide net royalties on sales of RotarixÒ 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

7

AVANT, then AVANT will receive 92.5% of all additional royalties. If RotarixÒ 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.

On March 14, 2006, AVANT amended its agreement with PRF to accelerate the \$40 million milestone payment, which was received on March 17, 2006. The payment had previously been due upon the first sale of RotarixÒ in the European Union, which was expected to occur during the second quarter of 2006. Other financial terms of the PRF agreement were not changed.

In September 2006, AVANT received notice from Glaxo that Glaxo would begin paying royalties on sales of RotarixÒ vaccine at the lower of two royalty rates under their 1997 license agreement. Glaxo's decision to pay the lower royalty rate (which is 70% of the full rate) is based upon Glaxo's assertion that RotarixÒ is not covered by the patents Glaxo licensed from AVANT in Australia and certain European countries. If Glaxo's position stands, the royalties to which PRF is entitled will no longer be limited by a \$27.5 million annual threshold, which AVANT projected may have been reached in later years as sales of RotarixÒ increase. Irrespective of Glaxo's position, AVANT will still retain the royalties on worldwide sales of RotarixÒ once PRF receives 2.45 times the aggregate cash payments it makes to AVANT, though the potential amount of such residual royalties will be lower if Glaxo's position stands.

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 and the \$40 million milestone payment for launch in the European Union were recorded by AVANT as deferred revenue upon receipt. 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 light of then current events and circumstances. In February 2006, the European Commission granted approval of RotarixÒ in the European Union, which triggered a \$4 million milestone payment from Glaxo, 50% of which is creditable against future royalties. AVANT remitted \$1.4 million of the Glaxo milestone payment to PRF in accordance with the PRF agreement. As a result, in the first quarter of 2006, AVANT recognized \$550,803 in product royalty revenue related to PRF's purchased interests in the net royalties that AVANT receives from RotarixÒ worldwide net sales. Based on management's best estimates of the amount and timing of Glaxo royalties, the Company has classified \$4,415,582 and \$45,033,615 of the deferred revenue balance at September 30, 2006 as short-term and long-term, respectively.

# (5) <u>Stock-Based Compensation</u>

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," ("SFAS 123(R)") which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options and employee stock purchases related to the Employee Stock Purchase Plan ("employee stock purchases") based on estimated fair values. SFAS 123(R) supersedes the Company's previous accounting under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 ("SAB 107") relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's fiscal year 2006. The Company's Consolidated Financial Statements as of and for the three and nine months ended September 30, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Company's Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Stock-based compensation expense recognized under SFAS 123(R) for the three months ended September 30, 2006 was \$413,401, which consisted of stock-based compensation expense related to employee and non-employee director stock options and restricted stock units of \$106,667 and \$306,250, respectively. Stock-based compensation expense recognized under SFAS 123(R) for the nine months ended September 30, 2006 was \$953,297, which consisted of stock-based compensation expense related to employee and non-employee director stock options and restricted

8

stock units of \$293,158 and \$656,250, respectively. There was no stock-based compensation expense related to employee and non-employee director stock options and employee stock purchases recognized during the three and nine months ended September 30, 2005. Stock-based compensation expense of \$121,000 and \$363,000 related to restricted stock unit awards was recognized during the three and nine months ended September 30, 2005, respectively. No significant stock-based compensation expenses were recorded for employee stock purchases.

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's Consolidated Statement of Operations. Prior to the adoption of SFAS 123(R), the Company accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). Under the intrinsic value method, no stock-based compensation expense had been recognized in the Company's Consolidated Statement of Operations because the exercise price of the Company's stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant.

Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest. Stock-based compensation expense recognized in the Company's Consolidated Statement of Operations for the three and nine months ended September 30, 2006 included compensation expense for share-based payment awards granted prior to, but not yet vested as of January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). In conjunction with the adoption of SFAS 123(R), compensation expense for all share-based payment awards granted prior to January 1, 2006 will continue to be recognized using the straight-line method and compensation expense for all share-based payment awards granted subsequent to January 1, 2006 will also be recognized using the straight-line method. As stock-based compensation expense recognized in the Consolidated Statement of Operations for the first nine months of fiscal 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In the Company's pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

Upon adoption of SFAS 123(R), the Company retained its method of valuation for share-based awards granted beginning in fiscal 2006 using the Black-Scholes option-pricing model ("Black-Scholes model") which was previously used for the Company's pro forma information required under SFAS 123. The Company's determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the Company's stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company's expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors.

The Company has not recognized any tax benefits or deductions related to the tax effects of employee stock-based compensation as the Company carries a full deferred tax asset valuation allowance and has significant net operating loss carryforwards available.

#### **Employee Stock Benefit Plans**

#### **Restricted Stock Unit Awards**

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 the remaining months until Dr. Ryan attains age 65 in December 2006, and is being recorded as compensation expense. In connection with the award, the Company has recognized \$54,000 and \$162,000 as stock-based compensation expense in the statements of operations during the three- and nine-month periods ended September 30, 2006, respectively. 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. On September 21, 2006, the Company's Board of Directors modified these Restricted Stock Units to provide that they vest in their entirety upon the earlier of the sale of the Company or Dr. Ryan's retirement at or after age 65. The value of the Restricted Stock Units is being amortized over the remaining months until Dr. Ryan attains age 65 in December 2006 and is being recorded as compensation expense. In connection with the awards, the Company has recognized \$252,250 and \$494,250 and \$121,000 and \$363,000 as stock-based compensation expense in the statements of operations during the three- and nine-month periods ended September 30, 2006 and 2005, respectively.

AVANT has applied an estimated forfeiture rate of zero to the restricted stock unit awards.

#### **Employee Stock Purchase Plan**

The 2004 Employee Stock Purchase Plan (the "2004 Plan") was adopted on May 13, 2004. All full time employees of AVANT are eligible to participate in the 2004 Plan. A total of 150,000 shares of common stock are reserved for issuance under the 2004 Plan. Under the 2004 Plan, each participating employee may contribute up to 15% of his or her compensation to purchase up to 500 shares of common stock per year in any six-month offering period and may withdraw from the offering at any time before stock is purchased. Participation terminates automatically upon termination of employment. The purchase price per share of common stock in an offering is 85% of the lower of its fair market value at either the beginning of the offering period or the applicable exercise date. During the nine months ended September 30, 2006 and 2005, the Company issued 5,665 and 3,403 shares, respectively, under the 2004 Plan. At September 30, 2006, 126,757 shares were available for issuance under the 2004 Plan.

The 2004 Plan is a compensatory plan under SFAS 123R. The requisite service period for compensation cost resulting from the 2004 Plan is the period over which the employee participates in the plan and pays for the shares. AVANT has historically established two purchase periods during each year—January 1 to June 30 and July 1 to December 31. The requisite service period begins on the enrollment date (the start of the offering period) and ends on the purchase date and is determined to be six months.

The current purchase period began on July 1, 2006. The Company has established the risk-free interest rate assumption to be 5.3% using the 6-month rate on a traded zero-coupon U.S. Treasury bond. The Company used its historical volatility rate of 51% for the 6-month period preceding the grant date for the current stock purchase period. The Company has concluded that volatility during the current purchase period is expected to be consistent with the calculated historical volatility rate. Finally, the Company established the expected term for the current stock purchase period as six months. Based on these assumptions, the Company has calculated and expensed the fair value for the 2,500 shares in the current stock purchase period which amounted to \$484 for the three months ended September 30, 2006.

#### **Employee Stock Option Plans**

#### Stock Option Plan Description

On May 6, 1999, AVANT's 1999 Stock Option and Incentive Plan (the "1999 Plan") was adopted. The 1999 Plan replaced the Amended and Restated 1991 Stock Compensation Plan, which was an amendment and restatement of AVANT's 1985 Incentive Option Plan. The 1999 Plan permits the granting of incentive stock options (intended to qualify as such under Section 422A of the Internal Revenue Code of 1986, as amended), non-qualified stock options, stock appreciation rights, performance share units, restricted stock and other awards of restricted stock in lieu of cash bonuses to employees, consultants and outside directors.

The 1999 Plan, as amended in 2002, allows for a maximum of 3,500,000 shares of common stock to be issued prior to May 6, 2009. The Board of Directors determines the term of each option, option price, and number of shares for which each option is granted and the rate at which each option vests. The Board of Directors has granted employee stock option awards with four-year vesting periods. The term of each option cannot exceed ten years (five years for options granted to holders of more than 10% of the voting stock of AVANT) and the exercise price of stock options cannot be less than the fair

1	Λ
L	υ

market value of the common stock at the date of grant (110% of fair market value for incentive stock options granted to holders of more than 10% of the voting stock of AVANT). Vesting of all employee stock option awards is accelerated upon a change in control as defined in the 1999 Plan.

The 1999 Plan provides for the automatic grant of non-qualified stock options to non-employee directors. Each non-employee director who is serving as a director of the Company on the fifth business day after each annual meeting of stockholders will automatically be granted on such day a non-qualified stock option to acquire 10,000 shares of common stock. The exercise price of each such non-qualified stock option is the fair market value of common stock on the date of grant. Each such non-qualified stock option is exercisable on the first anniversary of the grant date. Such non-qualified stock options will expire ten years from the date of grant. The 1999 Plan also provides for discretionary grants of non-qualified stock options to non-employee directors. Vesting of all non-employee director stock option awards is accelerated upon a change in control as defined in the 1999 Plan.

On November 17, 2005, pursuant to and in accordance with the recommendation of the Compensation Committee, the Board of Directors of AVANT approved full acceleration of the vesting of otherwise unvested stock options that had an exercise price of \$2.00 or greater granted under the 1999 Plan that were held by employees, officers and non-employee directors. As a result of the Board of Directors' action, a total of 265,935 of such "out-of-the-money" unvested stock options, having a weighted average exercise price of \$2.37 per share, became exercisable effective November 17, 2005, rather than the later dates when such options would have vested in the normal course. The Company determined the value of the "out-of-the-money" unvested stock options to be \$360,100. This action was taken in accordance with the applicable provisions of the 1999 Plan. The Board's decision to accelerate the vesting of these "out-of-the-money" stock options was made primarily to reduce compensation expense that otherwise would be recorded in future periods following AVANT's adoption in the first quarter of 2006 of SFAS 123R.

A summary of stock option activity for the nine months ended September 30, 2006 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Outstanding at January 1,	2,974,950	\$ 2.55	4.86
Granted	667,950	1.96	9.34
Exercised	(4,188)	1.23	—
Canceled/forfeited	(14,824)	1.89	—
Expired	(322,547)	2.93	—
Outstanding at September 30,	3,301,341	\$ 2.40	5.53
At September 30,			
Options exercisable	2,416,721	\$ 2.59	
Available for grant	1,405,266		
Weighted average fair value of options granted during nine-month period		\$ 1.46	

The aggregate intrinsic value of options outstanding at September 30, 2006 was \$34,467, of which \$26,053 related to exercisable options.

#### Valuation and Expense Information under SFAS 123(R)

The following table summarizes stock-based compensation expense related to employee and non-employee director stock options, employee stock purchases and restricted stock unit awards under SFAS 123(R) for the three and nine months ended September 30, 2006 which was allocated as follows:

#### 11

	Three Months Ended September 30, 2006		Nine Months Ended September 30, 2006	
Research and development	\$ 39,970	\$	113,098	
General and administrative	373,431		840,199	
Total stock-based compensation expense	\$ 413,401	\$	953,297	

Stock-based compensation expense recognized for the three months ended September 30, 2006 and 2005 included \$306,250 and \$121,000, respectively, related to restricted stock unit awards, all of which were allocated to general and administrative expenses. Stock-based compensation expense recognized for the nine months ended September 30, 2006 and 2005 included \$656,250 and \$363,000, respectively, related to restricted stock unit awards, all of which were allocated to general and administrative expenses.

Based on basic and diluted weighted average common shares outstanding of 74,182,347 and 74,176,593 for the three- and nine-month periods, respectively, the effect of stock-based compensation expense recorded under SFAS 123R was approximately \$0.01 per share.

The table below reflects the pro forma information for the three and nine months ended September 30, 2005 as follows:

	-	hree Months Ended eptember 30, 2005	-	Nine Months Ended eptember 30, 2005
Net Loss:				
As reported for prior years	\$	4,514,434	\$	14,116,872
Less: Stock-based employee compensation expense as reported		(121,000)		(363,000)
Add: Total stock-based employee compensation expense determined under fair value based method for all awards		221,412		728,636
Net loss, including the effect of stock-based compensation expense	\$	4,614,846	\$	14,482,508
Basic and diluted net loss per share — as reported for prior periods	\$	0.06	\$	0.19
Basic and diluted net loss per share, including the effect of stock-based compensation expense	\$	0.06	\$	0.20

As of September 30, 2006, total compensation cost related to non-vested stock options not yet recognized was \$775,090 which is expected to be recognized as expense over a weighted average period of 2.3 years. As of September 30, 2006, total compensation cost related to non-vested restricted stock unit awards not yet recognized was \$962,000 which is expected to be recognized over a weighted average period of 0.3 years.

The fair values of employee stock options granted during the three and nine months ended September 30, 2006 and 2005 were valued using the Black-Scholes model with the following assumptions:

	Three months ended September 30,		Nine months o September	
	2006	2005	2006	2005
Expected stock price volatility (employees)	76%	81%	76%	81%
Expected stock price volatility (non-employee directors)	—	81%	76%	81%
Expected option term (employees)	6.25 Years	4.5 Years	6.25 Years	4.5 Years
Expected option term (non-employee directors)	—	4.5 Years	5.5 Years	4.5 Years

Risk-free interest rate	4.5 -5.2%	3.8 - 4.3%	4.3 - 5.2%	3.6 - 4.3%
Expected dividend yield	None	None	None	None

12

The Company used its historical stock price volatility as the basis for its expected volatility assumption consistent with SFAS 123(R) and SAB 107 for its employee and non-employee director stock options and employee stock purchases. Prior to fiscal 2006, the Company had also used its historical stock price volatility in accordance with SFAS 123 for purposes of its pro forma information. The Company has assessed that its historical volatility is representative of expected future stock price trends.

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the Company's employee and nonemplyee director stock options and employee stock purchases. The dividend yield assumption is based on the Company's history of zero dividend payouts and expectation that no dividends will be paid in the foreseeable future.

The expected term of employee and non-employee director stock options represents the weighted-average period the stock options are expected to remain outstanding. SAB 107 provides for a simplified method for estimating expected term for "plain-vanilla" options. The simplified method is based on the vesting period and the contractual term for each grant or for each vesting tranche for awards with graded vesting. The mid-point between the vesting date and the expiration date is used as the expected term under this method. The Company has elected to follow the guidance of SAB 107 and adopt this simplified method in determining expected term for its stock option awards. There were 70,000 stock option grants to non-employee directors during the nine months ended September 30, 2006.

Forfeitures were estimated based on historical experience by applying a 10 and zero percent forfeiture rate to employee and non-employee director stock option awards granted during the nine months ended September 30, 2006, respectively.

#### (6) <u>Accounts Receivable</u>

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company has not historically experienced credit losses from its accounts receivable and therefore has not established an allowance for doubtful accounts. The Company does not have any off-balance-sheet credit exposure related to its customers.

Accounts receivable consists of the following:

	September 30, 2006		December 31, 2005	
Trade	\$	350,501	\$	383,416
Other		203,857		34,964
	\$	554,358	\$	418,380

Other receivables at September 30, 2006 represent interest receivable from a bank and a receivable due from the Company's Needham landlord. Other receivables at December 31, 2005 represent interest receivable from a bank.

#### (7) <u>Property and Equipment</u>

Property and equipment includes the following:

	September 30, 2006	December 31, 2005
Laboratory Equipment	\$ 3,172,317	\$ 2,966,354
Manufacturing Equipment	1,765,833	1,054,512
Office Furniture and Equipment	1,048,973	1,893,623
Leasehold Improvements	4,710,849	4,510,075
Construction in Progress	4,991,826	960,624
Total Property and Equipment	15,689,798	11,385,188
Less Accumulated Depreciation and Amortization	(5,155,426)	(5,641,525)
	\$10,534,372	\$ 5,743,663

The Company has recognized \$25,521 and \$67,493 of capitalized interest costs incurred in financing leasehold improvements and laboratory and manufacturing equipment at its Fall River and Needham facilities during the three- and nine-month periods ended September 30, 2006, respectively. The total amount of interest expense incurred by AVANT during the three- and nine-month periods was \$25,521 and \$77,973, respectively.

Depreciation expense related to equipment and leasehold improvements was \$293,478 and \$206,591 for the three months ended September 30, 2006 and 2005, respectively, and \$780,493 and \$396,286 for the nine months ended September 30, 2006 and 2005, respectively.

## (8) Intangible and Other Assets

Intangible and other assets include the following:

	Septembe	r 30, 2006	December 31, 2005				
Estimated Lives	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	
5 years	\$ 1,090,000	\$ (1,090,000) \$	3⁄4	\$ 1,090,000	\$ (1,090,000) \$	3⁄4	
10 years	3,786,900	(1,792,372)	1,994,528	3,786,900	(1,508,352)	2,278,548	
7 years	3,263,100	(2,716,000)	547,100	3,263,100	(2,366,800)	896,300	
17 years	2,563,900	(879,769)	1,684,131	2,563,900	(766,656)	1,797,244	
	10,703,900	(6, 478, 141)	4,225,759	10,703,900	(5,731,808)	4,972,092	
	94,981	3⁄4	94,981	94,981	3⁄4	94,981	
	\$10,798,881	\$ (6,478,141) \$	4,320,740	\$ 10,798,881	\$ (5,731,808) \$	5,067,073	
	5 years 10 years 7 years	Estimated Lives Gross Intangible Assets   5 years \$ 1,090,000   10 years 3,786,900   7 years 3,263,100   17 years 2,563,900   10,703,900 94,981	Estimated Lives Intangible Assets Accumulated Amortization   5 years \$ 1,090,000 \$ (1,090,000) \$   10 years 3,786,900 (1,792,372)   7 years 3,263,100 (2,716,000)   17 years 2,563,900 (879,769)   10,703,900 (6,478,141)   94,981 34	Gross Intangible Lives Accumulated Assets Net Intangible Assets   5 years \$ 1,090,000 \$ (1,090,000) \$ 34   10 years 3,786,900 (1,792,372) 1,994,528   7 years 3,263,100 (2,716,000) 547,100   17 years 2,563,900 (879,769) 1,684,131   10,703,900 (6,478,141) 4,225,759   94,981 34 94,981	Gross Intangible Lives Accumulated Assets Net Intangible Amortization Net Intangible Assets Gross Intangible Assets   5 years \$ 1,090,000 \$ (1,090,000) \$ 4 \$ 1,090,000   10 years 3,786,900 (1,792,372) 1,994,528 3,786,900   7 years 3,263,100 (2,716,000) 547,100 3,263,100   17 years 2,563,900 (879,769) 1,684,131 2,563,900   10,703,900 (6,478,141) 4,225,759 10,703,900   94,981 34 94,981 94,981	Gross Net Gross Accumulated Intangible Accumulated   Lives Assets Amortization Assets Intangible Accumulated   5 years \$ 1,090,000 \$ (1,090,000) \$ 4 \$ 1,090,000 \$ (1,090,000)   10 years 3,786,900 (1,792,372) 1,994,528 3,786,900 (1,508,352)   7 years 3,263,100 (2,716,000) 547,100 3,263,100 (2,366,800)   17 years 2,563,900 (879,769) 1,684,131 2,563,900 (766,656)   10,703,900 (6,478,141) 4,225,759 10,703,900 (5,731,808)   94,981 34 94,981 34	

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, 2006 and 2005, respectively.

The estimated future amortization expense of intangible assets as of September 30, 2006 for the remainder of fiscal year 2006 and the five succeeding years is as follows:

Year ending December 31,	Estimated Amortization Expense
2006 (remaining three months)	\$ 248,778
2007	960,212
2008	529,512
2009	529,512
2010	514,622
2011 and thereafter	1,443,123

#### (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. Potentially dilutive securities include stock options, warrants and restricted stock units. Options and warrants to purchase 3,745,785 and 3,549,365 shares of common stock and restricted stock units totaling 1,000,000 shares were not included in the computations of weighted average common shares for the periods ended September 30, 2006 and 2005, respectively, because inclusion of such shares would have an anti-dilutive effect on net loss per share.

# 14

#### (10) Income Taxes

The \$40 million milestone payment received from PRF during the first quarter of 2006 will result in taxable income for the Company. The regular taxable income generated by this transaction will be fully offset against available federal and state net operating loss carryforwards. The Company recorded a provision of \$372,000 in the first quarter of 2006 for the alternative minimum tax that will result from receipt of this milestone.

#### (11) <u>Product Development and Licensing Agreements</u>

AVANT's revenue from product development and licensing agreements was received pursuant to contracts with different organizations. A summary of these contracts follows:

# (A) GlaxoSmithKline plc ("Glaxo")

In 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. AVANT licensed-in the Rotarix® technology in 1995 and owes a license fee of 30% to Cincinnati Children's Hospital Medical Center ("CCH") on net royalties received from Glaxo. AVANT is obligated to maintain a license with CCH with respect to the Glaxo agreement. All licensing fees are included in research and development expense. The term of the Glaxo 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.

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 RotarixÒ (see Note 4). Under the PRF agreement, AVANT will retain 50% of future Glaxo milestone payments beginning on the effective date of the agreement with PRF, with 70% of the remaining balance payable to PRF and 30% of the remaining balance payable to CCH, respectively.

In February 2006, the European Commission granted approval of RotarixÒ in the European Union, which triggered a \$4 million milestone payment from Glaxo, 50% of which is creditable against future royalties. Revenue of \$2.6 million was recorded in the first quarter of 2006 as AVANT has no continuing obligations to incur any research and development costs in connection with the Glaxo agreement and the remaining \$1.4 million was remitted to PRF in accordance with the PRF agreement. In addition, the Company recorded \$600,000 of research and development expense in the first quarter of 2006 for

amounts which will be payable to CCH in connection with the aforementioned 2006 milestone payment. Glaxo has agreed to make further payments, which could total up to \$1.5 million, upon achievement of a specific milestone.

In September 2006, AVANT received notice from Glaxo that Glaxo would begin paying royalties on sales of RotarixÒ vaccine at the lower of two royalty rates under their 1997 license agreement. Glaxo's decision to pay the lower royalty rate (which is 70% of the full rate) is based upon Glaxo's assertion that RotarixÒ is not covered by the patents Glaxo licensed from AVANT in Australia and certain European countries.

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

The Company entered into a licensing agreement in December 2000 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.

As of June 1, 2006, AVANT entered into a Collaborative Research and Development Agreement with Pfizer aimed at the discovery and development of vaccines to protect animals. The collaboration will employ vaccine technologies owned by AVANT. Under the agreement, Pfizer and AVANT will conduct a joint research program funded by Pfizer to develop prophylactic and therapeutic vaccines to protect livestock and companion animals from respiratory and enteric diseases. AVANT considers its June 2006 arrangement with Pfizer to be a revenue arrangement with multiple deliverables. The Company expects to recognize revenue as the research and development service deliverables are completed and delivered to Pfizer.

15

#### (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 has recognized as revenue. 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.

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, 2006, 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 \$9.4 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, 2006 and 2005, AVANT recognized \$1,049,906 and \$1,942,709, respectively, in government contract revenue from DVC. Through September 30, 2006, AVANT had received approximately \$9.2 million in payments under the various subcontract agreements. These agreements expire in 2007, although they may be terminated by DVC at any time upon 30 days written notice.

#### (12) Other Long-Term Liabilities

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 Loan of \$1,227,800 to finance the build-out of its Fall River facility. Principal and interest payments on the loan are due monthly using an amortization period of 15 years and an interest rate of 5.5% per annum.

At September 30, 2006, AVANT has recorded leasehold improvements of \$1,227,800 and currently has a loan payable of \$1,084,557 to MassDevelopment, of which \$75,032 is classified as current and \$1,009,525 as long-term. AVANT began amortizing the leasehold improvements 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 is approximately \$781,600 at September 30, 2006.

#### (B) Note Payable

Under the Secured Promissory Note: Equipment Loan, AVANT received \$903,657 from MassDevelopment to finance the purchases of manufacturing and laboratory equipment to be placed in its 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. The net book value of these collateralized assets at September 30, 2006 and December 31, 2005 was \$795,830 and \$880,690, respectively.

At September 30, 2006, AVANT currently has a note payable of \$694,466 to MassDevelopment, of which \$129,859 is classified as current and \$564,607 as long-term. AVANT began depreciating the manufacturing and laboratory equipment assets over the estimated economic lives of the assets when the equipment became ready for its intended use. 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 \$610,600 at September 30, 2006.

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

#### (A) Commitments for the Renovations of the Needham Facility and Improvements to the Fall River Facility

In November 2005, AVANT entered into a Lease Amendment with the landlord which specified terms for the complete renovation of the Company's Needham facility. The current projected costs for the tenant improvements portion of the renovations project are approximately \$9.1 million. As an incentive for AVANT to enter into the Lease Amendment, the landlord has agreed to contribute up to \$3.6 million towards tenant improvement costs. The Company will record the full cost of the Needham renovation project as an asset and the amounts of landlord incentive will be recorded as deferred rent (included under "Other Long Term Liabilities" account in the consolidated balance sheets) in accordance with FASB Technical Bulletin 88-1 "Issues Related to Accounting for Leases." Amortization of the deferred rent will be recorded as a reduction of rent expense over the remaining lease term when the renovation project is complete and will be classified as an operating activity in the Consolidated Statement of Cash Flows.

In November 2005, AVANT amended the MassDevelopment lease to increase the rentable space by approximately 2,500 square feet to approximately 14,300 square feet at the Fall River facility. The landlord is providing a tenant incentive allowance of \$49,740 against the cost of alterations and improvements required by AVANT to be made to the expanded space. As of September 30, 2006, none of the tenant incentive allowance has been received. In April 2006, AVANT entered into a Design/Build Contract with a design/builder for the build-out of the expanded space. The contract amount totals \$345,000 and the construction project was completed in the third quarter of 2006.

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

In April 2000, AVANT entered into a Services Agreement (the "Lonza Agreement") with Lonza Biologics plc ("Lonza") for process development and manufacture of its product candidate TP10. 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, 2006 total approximately \$1,011,656. The Company has incurred \$1,348,356 and \$8,129,077, respectively, of expense related to the Lonza Agreement in the nine-month period ended September 30, 2006 and from inception through September 30, 2006, of which \$190,768 remained accrued at September 30, 2006.

17

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, ETEC E. coli and other products; (4) the cost, timing, scope and results of ongoing safety and efficacy trials of TP10, CETi-1, CholeraGarde® (Peru-15), Ty800, ETEC E. coli 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, ETEC E. coli 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®Eqg and other future products; (8) the process of obtaining regulatory approval for the sale of RotarixO in major commercial markets, as well as the timing and success of worldwide commercialization of RotarixÒ by our partner, Glaxo; (9) Glaxo's strategy and business plans to launch and supply Rotarix® worldwide, including in the U.S. and other major markets and its payment of royalties to AVANT; (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, ETEC E. coli, 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; (16) AVANT's expectations regarding research and development expenses and general and administrative expenses; (17) DVC's ability to complete clinical trials and perform under its agreement; (18) AVANT's expectations regarding CETP's ability to improve cholesterol levels and AVANT's ability to develop and commercialize CETP; (19) AVANT's expectations regarding cash balances, anticipated royalty payments (including those from Glaxo) and expenses, including infrastructure expenses; and (20) 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 2005 Form 10-K. Other than the adoption of Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," ("SFAS 123(R)"), there has been no changes to these policies since December 31, 2005. Readers are encouraged to review these critical accounting policies in conjunction with the review of this Form 10-Q.

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," ("SFAS 123(R)") which requires the measurement and recognition of compensation expense for all share-based payment awards made to its employees and directors including employee stock options and employee stock purchases related to the 2004 Employee Stock Purchase Plan ("employee stock purchases") based on estimated fair values. The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's fiscal year 2006. The Company's Consolidated

Financial Statements as of and for the three and nine months ended September 30, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Company's Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Stock-based compensation expense recognized under SFAS 123(R) for the three months ended September 30, 2006 was \$413,401, which consisted of stock-based compensation expense related to employee and non-employee director stock options and restricted stock units of \$106,667 and \$306,250, respectively. Stock-based compensation expense recognized under SFAS 123(R) for the nine months ended September 30, 2006 was \$953,297, which consisted of stock-based compensation expense related to employee and non-employee director stock options and restricted stock units of \$293,158 and \$656,250, respectively. There was no stock-based compensation expense related to employee and non-employee director stock options and restricted stock units of \$121,000 and \$363,000 related to restricted stock unit awards was recognized during the three and six months ended September 30, 2005, respectively. Stock-based compensation expense of \$953,297 and \$363,000 was reflected as operating cash flows in the Consolidated Statements of Cash Flows for the nine months ended September 30, 2006 and 2005, respectively. See Note 4 to the Consolidated Financial Statements for additional information. No significant stock-based compensation expenses.

The determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to the expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. The weighted average estimated fair value of employee stock options granted during the three and nine months ended September 30, 2006 was \$1.05 and \$1.46, respectively, per share using the Black-Scholes option pricing model with the following assumptions:

	Three months ended September 30, 2006	Nine months ended September 30, 2006
Expected stock price volatility (employees)	76%	76%
Expected stock price volatility (non-employee directors)	—	76%
Expected option term (employees)	6.25 Years	6.25 Years
Expected option term (non-employee directors)	—	5.5 Years
Risk-free interest rate	4.5 - 5.2%	4.3 — 5.2%
Expected dividend yield	None	None

The Company used its historical stock price volatility as the basis for its expected volatility assumption consistent with SFAS 123(R) and SAB 107 for its employee and non-employee director stock options and employee stock purchases. Prior to fiscal 2006, the Company had also used its historical stock price volatility in accordance with SFAS 123 for purposes of its pro forma information. The Company has assessed that its historical volatility is representative of expected future stock price trends.

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the Company's employee and nonemployee director stock options and employee stock purchases. The dividend yield assumption is based on the Company's history of zero dividend payouts and expectation that no dividends will be paid in the foreseeable future.

The expected term of employee and non-employee director stock options represents the weighted-average period the stock options are expected to remain outstanding. SAB 107 provides for a simplified method for estimating expected term for "plain-vanilla" options. The simplified method is based on the vesting period and the contractual term for each grant or for each vesting tranche for awards with graded vesting. The mid-point between the vesting date and the expiration date is used as the expected term under this method. The Company has elected to follow the guidance of SAB 107 and adopt this simplified method in determining expected term for its stock option awards. There were 70,000 stock option grants to non-employee directors during the nine months ended September 30, 2006.

Forfeitures were estimated based on historical experience by applying a 10 and zero percent forfeiture rate to employee and non-employee director stock option awards granted during the nine months ended September 30, 2006, respectively.

19

If factors change and we employ different assumptions in the application of SFAS 123(R) in future periods, the compensation expense that we record under SFAS 123(R) may differ significantly from what we have recorded in the current period.

# **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 immuno-therapeutics. These include an oral human rotavirus vaccine, which gained its first marketing approval in Mexico in July 2004 and is being marketed by Glaxo worldwide. Five 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 the CETP vaccine and the marriage of innovative bacterial vector delivery technologies with unique manufacturing

processes offer 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 the U.S.'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 2005, AVANT incurred an aggregate of \$74 million in research and development costs. During the nine months ended September 30, 2006, AVANT incurred an aggregate of \$13.4 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, 2005 and 2004 and the nine-month periods ended September 30, 2006 and 2005. 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 Septembere 30,				_	Years Ended December 31,			
	2006		2005		2005			2004	
Bacterial Vaccines:									
CholeraGardeÒ	\$	3,240,200	\$	707,500	\$	1,257,200	\$	123,100	
Ty800		619,700		334,900		404,500		688,300	
Other		1,287,400		348,300		528,900		332,500	
BioDefense Vaccines:		1,413,700		1,839,200		2,470,700		3,082,800	
Cholesterol Management Vaccine:									
CETi-1		834,000		458,500		650,800		816,900	
Complement Inhibitors:									
TP10/TP20		3,722,800		6,973,000		8,327,200		7,706,300	
Food Safety & Animal Health Vaccines:		6,200		7,000		9,900		12,600	
Viral Vaccines:									
RotarixÒ vaccine		648,600						500,000	
Avian Flu		585,400							
TheraporeÒ/HIV		_		4,900		11,800		184,900	
Other Programs:		871,000		379,700		402,300		426,400	
Total R&D Expense	\$	13,229,000	\$	11,053,000	\$	14,063,300	\$	13,873,800	

#### 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 RotarixÒ in Mexico in July 2004, which represents the first in an expected series of worldwide approvals and commercial launches for the product. Glaxo has launched in additional Latin American and Asian Pacific countries during 2005 and 2006. Additionally, Glaxo filed for market approval with the European regulatory authorities in late 2004, which triggered a \$2 million milestone payment to AVANT. In February 2006, the European Commission granted approval of RotarixÒ in the European Union, which triggered a \$4 million milestone payment from Glaxo. Glaxo has agreed to make an additional payment of \$1.5 million, upon achievement of market approval in the United States. AVANT licensed-in the Rotarix® technology in 1995 and owes a license fee of 30% to Cincinnati Children's Hospital Medical Center ("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 RotarixÒ (see Note 3 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.

On March 14, 2006, AVANT amended its agreement with PRF to accelerate the \$40 million milestone payment, which was received on March 17, 2006. The payment had previously been due upon the first sale of RotarixÒ in the European Union, which was expected to occur during the second quarter of 2006. Other financial terms of the PRF agreement were not changed.

In September 2006, AVANT received notice from Glaxo that Glaxo would begin paying royalties on sales of RotarixÒ vaccine at the lower of two royalty rates under their 1997 license agreement. Glaxo's decision to pay the lower royalty rate (which is 70% of the full rate) is based upon Glaxo's assertion that RotarixÒ is not covered by the patents Glaxo licensed from AVANT in Australia and certain European countries.

*Complement Inhibitors:* TP10, a soluble form of naturally occurring Complement Receptor 1, has effectively shown to inhibit the activation of the complement cascade in animal models. AVANT believes that regulating the complement system could have therapeutic and prophylactic applications in several acute and chronic conditions, including reperfusion injury from surgery or ischemic disease, organ transplant, multiple sclerosis, rheumatoid arthritis, and myasthenia gravis. AVANT has elected to develop TP10 for cardiac surgery. In February 2002, AVANT announced that TP10 had not achieved a

significant reduction in the primary endpoint of a Phase 2 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 2b double-blind, placebo-controlled trial of TP10 in approximately 300 women undergoing cardiopulmonary by-pass surgery. In February 2006, AVANT reported that the females-only study did not meet the primary endpoint, thus confirming the results for female subjects in the previous TP10 trial. Therefore, given the strong efficacy data in males shown in this previous study, AVANT believes there is a clear clinical development pathway for a males-only indication for TP10 in cardiac bypass surgery. Males represent 75% of the U.S. market opportunity in cardiac bypass surgery. AVANT believes that the TP10 program is now well positioned for a males-only cardiac bypass surgery indication. AVANT is currently seeking a corporate partner to complete development and to commercialize TP10.

During the period January 1, 2001 through December 31, 2005, AVANT incurred approximately \$32.3 million in research, development, contract manufacturing and clinical costs associated with its complement inhibitor program. During the nine months ended September 30, 2006, the Company incurred approximately \$3.7 million in research, development, contract manufacturing and clinical costs associated with its complement, contract manufacturing and clinical costs associated with its complement, contract manufacturing and clinical costs associated with its complement.

*Bacterial Vaccines:* AVANT's goal is to become a leading developer of innovative vaccines that address health care needs on a global basis. In this regard, AVANT acquired VitriLife®, a technology with the potential to reduce manufacturing costs and improve product stability, and potentially eliminating the need for vaccine refrigeration during shipping and storage. With this and other drying and preservation technologies and AVANT's *Cholera*- and *Salmonella*-vectored delivery technologies, named VibrioVecÒ and SalmoVec<sup>TM</sup>, the Company can now develop a new generation of vaccines that have an ideal product profile: safe, effective, oral, single-dose, rapidly protective and increased thermostability.

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 2 dose-ranging study with CholeraGarde® which confirmed the safety and activity of this vaccine and supported the start of Phase 2 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® 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. AVANT is preparing for a CholeraGarde® Phase 3 clinical study in the U.S. planned for mid-year 2007.

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® formulation to CholeraGarde®. In the future, AVANT plans to utilize VitriLife®, a proprietary technology that confers thermostability to live bacterial vaccines, and other drying and preservation technologies at the Fall River facility for its other bacterial vaccines.

During the period January 1, 2001 through December 31, 2005, AVANT incurred approximately \$10.4 million in research, development and clinical costs on its CholeraGarde® program. During the nine months ended September 30, 2006, AVANT incurred approximately \$3.2 million in research, development, manufacturing and clinical costs on its CholeraGarde® program.

AVANT is also developing an oral typhoid fever vaccine, Ty800, for global health needs. The National Institute of Allergy and Infectious Disease ("NIAID") of the National Institutes of Health ("NIH") and AVANT agreed for the NIAID to conduct a Phase 1/2 in-patient dose-ranging clinical trial aimed at demonstrating the safety and immunogenicity of the Ty800 vaccine. NIAID funded the production of Ty800 vaccine for clinical testing and initiated the Phase 1/2 trial at a NIH-funded clinical site in February 2006. The NIAID trial seeks to confirm the safety and immunogenicity of the Ty800 vaccine study. Enrollment in this study was completed during the third quarter of 2006. During the period January 1, 2001 through December 31, 2005, AVANT incurred approximately

22

\$5.3 million in research, development, contract manufacturing and clinical costs on its Ty800 program. During the nine months ended September 30, 2006, AVANT incurred approximately \$619,700 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 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 provided approximately \$107,000 in funding and work was completed by AVANT during the second quarter of 2006. During the period January 1, 2001 through December 31, 2005, AVANT incurred approximately \$1.2 million in research, development and clinical costs on these pre-clinical programs. During the nine months ended September 30, 2006, AVANT incurred approximately \$1.3 million 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. 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 that 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 DVC LLC, formerly 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 1 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 1 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 June 30, 2006, AVANT has received a number of additional subcontract modifications from DVC to support pre-clinical 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 \$9.4 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, 2006 and 2005, AVANT recognized \$1,049,906 and \$1,942,709, respectively, in government contract revenue from DVC. Through September 30, 2006, AVANT had received approximately \$9.2 million in payments under the subcontract agreements. These agreements expire in 2007, although they may be terminated by DVC at any time upon 30 days notice.

During the period January 1, 2001 through December 31, 2005, AVANT incurred approximately \$9.3 million in research and development costs on its biodefense vaccine program. During the nine months ended September 30, 2006, AVANT incurred approximately \$1.4 million 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, 2001 through December 31, 2005, AVANT incurred approximately \$1.5 million in research and development costs on its food safety and animal health vaccines program. During the nine months ended September 30, 2006, AVANT incurred approximately \$6,200 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

23

developing this vaccine 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 often leads to heart attack.

In October 2003, AVANT completed a Phase 2 efficacy study of its CETi-1 vaccine 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, approximately 90%. In recent preclinical testing, AVANT has identified a new adjuvanted formulation for the vaccine that, when combined with a more immunogenic peptide sequence, in an animal study elicits more than a 10-fold increase in anti-CETP antibody titers in animal studies when compared to the previous vaccine formulation. AVANT has contracted for the production of GMP peptide for the newly formulated vaccine and expects to complete release and stability studies in 2006. During the period January 1, 2001 through December 31, 2005, AVANT incurred approximately \$10.4 million in research, development, contract manufacturing and clinical costs associated with the CETP program. During the nine months ended September 30, 2006, AVANT incurred approximately \$834,000 in research, development, contract manufacturing and clinical costs associated with the CETP program. AVANT plans to seek a corporate partner to complete development and to commercialize the CETP 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.

# **RESULTS OF OPERATIONS**

# Three-Month Period Ended September 30, 2006 as Compared with the Three-Month Period Ended September 30, 2005

AVANT reported consolidated net loss of \$5,520,567, or \$.07 per share, for the third quarter ended September 30, 2006, compared with a net loss of \$4,514,434, or \$.06 per share, for the third quarter ended September 30, 2005. The weighted average common shares outstanding used to calculate net loss per common share was 74,182,347 in 2006 and 74,145,814 in 2005.

*Revenue:* Total revenue decreased \$507,323 to \$338,999 for the third quarter of 2006 compared to \$846,322 for the third quarter of 2005.

Product development and licensing revenue decreased \$43,217 to \$35,475 in 2006 from \$78,692 in 2005 due to a decrease in reimbursed patent expense by AVANT's partner, Pfizer.

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 \$280,419 and \$767,630 in government contract and grant revenue during the third quarters of 2006 and 2005, respectively, for work performed. The decrease in revenue in 2006 compared to 2005 primarily reflects reduced levels of vaccine development work billable to DVC in 2006.

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 March 2005, the USDA placed a stop sale order on MeganÒVac 1 and MeganÒEgg for LAHI's failure to update the Outline of Production as LAHI 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. Royalty payments received during the third quarter of 2006 totaled \$23,105 and no royalty payments were received during the third quarter of 2005.

*Operating Expense:* Total operating expense increased \$973,479, or 17.7%, to \$6,483,897 for the third quarter of 2006 compared to \$5,510,418 for the third quarter of 2005.

Research and development expense increased \$824,986, or 23.0%, to \$4,416,320 from \$3,591,334 in 2005. The increase in 2006 compared to 2005 is primarily due to increases in research and development personnel and related costs of \$457,839, laboratory materials and supplies of \$131,669, contract manufacturing costs incurred for TP10 process development and scale-up work of \$191,709 and non-personnel operating and facility-related costs of \$351,788 associated with operations of the Fall River facility in 2006 compared to 2005. These increases were offset in part by declines in clinical trials costs of \$605,892 associated with the TP10 program as a result of the completion of the TP10 Phase 2 female clinical trial.

General and administrative expense increased \$148,493, or 8.9%, to \$1,818,799 in 2006 compared to \$1,670,306 in 2005 and is primarily attributed to increases in stock-based compensation expense of \$252,431 and consulting costs of \$104,626, which were partly offset by a decrease in other personnel-related expenses of \$87,820 and legal and other professional fees of \$110,567.

Amortization expense of acquired intangible assets was \$248,778 in 2006 and 2005.

*Investment and Other Income, Net:* Interest and other income increased \$474,669 to \$624,331 for the third quarter of 2006 compared to \$149,662 for the third quarter of 2005. The increase is primarily due to higher interest rates and average cash balances during the third quarter of 2006 compared to the third quarter of 2005. During the third quarters of 2006 and 2005, the average month-end cash balances were \$49,378,137 and \$24,007,956, respectively. The effective interest rates during the third quarters of 2006 and 2005 were 5.09% and 3.27%, respectively.

# Nine-Month Period Ended September 30, 2006 as Compared with the Nine-Month Period Ended September 30, 2005

AVANT reported consolidated net loss of \$14,161,857, or \$.19 per share, for the nine months ended September 30, 2006, compared with a net loss of \$14,116,872, or \$.19 per share, for the nine months ended September 30, 2005. The weighted average common shares outstanding used to calculate net loss per common share was 74,176,593 in 2006 and 74,136,931 in 2005.

*Revenue*: Total revenue increased \$2,096,930 to \$4,550,965 for the first nine months of 2006 compared to \$2,454,035 for the first nine months of 2005.

Product development and licensing revenue increased \$2,463,686 to \$2,672,895 in 2006 from \$209,209 in 2005. In February 2006, the European Commission granted approval of RotarixÒ in the European Union, which triggered a one-time \$4 million milestone payment from Glaxo, 50% of which is creditable against future royalties. Product development and licensing revenue of \$2.6 million was recorded in the first quarter of 2006 and the remaining \$1.4 million was remitted to PRF in accordance with the PRF agreement. In the first quarter of 2006, AVANT recognized \$550,803 in product royalty revenue related to PRF's purchased interests in the net royalties that AVANT receives from RotarixÒ worldwide net sales.

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 \$1,241,149 and \$2,156,680 in government contract and grant revenue during the first nine months of 2006 and 2005, respectively, for work performed. The decrease in revenue in 2006 compared to 2005 primarily reflects reduced levels of vaccine development work billable to DVC in 2006. AVANT expects the amount of research work to be performed for DVC during the remainder of 2006 to decrease from the amount of research work performed during the fourth quarter of 2005.

Marketing and distribution of the Megan poultry product line is performed by AVANT's partner, Lohmann Animal Health International ("LAHI"), and AVANT receives a royalty percentage of all Megan®Vac 1 and Megan®Egg product sales. Royalty payments received during the first nine months of 2006 and 2005 totaled \$86,117 and \$88,146, respectively. AVANT expects royalty payments from LAHI to be approximately the same in the fourth quarter of 2006 compared to 2005.

25

*Operating Expense:* Total operating expense increased \$2,858,302, or 16.8%, to \$19,899,765 for the first nine months of 2006 compared to \$17,041,463 for the first nine months of 2005.

Research and development expense increased \$2,175,982, or 19.7%, to \$13,228,926 for the first nine months of 2006 from \$11,052,944 for the first nine months of 2005. The increase in 2006 compared to 2005 is primarily due to \$600,000 of license fee expense recorded in the first quarter of 2006 for amounts which will be payable to CCH in connection with the aforementioned 2006 Glaxo milestone payment. The Company also experienced increases in research and development personnel and related costs of \$1,339,418, consultant fees of \$214,614, contract research costs of \$326,137, other license fees of \$148,566, and non-personnel operating and facility-related costs of \$756,004 associated with operations of the Fall River facility in 2006 compared to 2005. These increases were offset in part by a decrease in clinical trials costs of \$1,542,025 associated with the TP10 program as a result of the completion of the TP10 Phase 2 female clinical trial. AVANT expects research and development expense to increase substantially in the fourth quarter of 2006 as AVANT prepares for a CholeraGardeÒ Phase 3 trial starting in mid-year 2007 and as the Fall River facility runs at full operational status.

General and administrative expense increased \$682,320, or 13.0%, to \$5,924,505 for the first nine months of 2006 compared to \$5,242,185 in 2005 and is primarily attributed to increases in stock-based compensation expense of \$477,198, consultant fees of \$145,603 and investor relations expenses of \$89,388. These increases are partly offset by a decrease in legal and other professional fees of \$142,692. AVANT expects general and administrative expense to continue at this level for the remainder of 2006.

Amortization expense of acquired intangible assets was \$746,334 in the first nine months of 2006 and 2005.

*Investment and Other Income, Net:* Interest and other income increased by \$1,088,387 to \$1,558,943 for the first nine months of 2006 compared to \$470,556 for the first nine months of 2005. The increase is primarily due to higher interest rates and average cash balances during the first nine months of 2006 compared to the first nine months of 2005. During the first nine months of 2006 and 2005, the average month-end cash balances were \$46,441,661 and \$26,948,666, respectively. The effective interest rates during the first nine months of 2006 and 2005 were 4.68% and 2.80%, respectively.

*Provision for Income Taxes:* The \$40 million milestone payment received from PRF during the first quarter of 2006 will result in taxable income for the Company. The regular taxable income generated by this transaction has been fully offset with available federal and state net operating loss carryforwards. The Company recorded a provision of \$372,000 in the first quarter of 2006 for the alternative minimum tax that will result from receipt of this milestone.

# LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2006, AVANT's principal sources of liquidity consisted of cash and cash equivalents of \$46,681,330. 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. Also, the Company maintains cash balances with financial institutions in excess of insured limits. AVANT does not anticipate any losses with respect to such cash balances.

The use of AVANT's cash flows for operations has primarily consisted of salaries and wages for its employees, facility and facility-related costs for its offices, 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 provided by operating activities increased to \$28,973,524 for the first nine months of 2006 compared to net cash used in operating activities of \$8,090,620 for the first nine months of 2005. The increase is primarily attributed to the net increase in deferred revenue of \$39,586,697 related primarily to the \$40 million PRF milestone payment received in the first

<b>`</b>	c
2	b
_	-

quarter of 2006. These amounts were offset partly by the increase in accounts receivable and the increase in net loss incurred in 2006 compared to 2005. Other than the effect of receiving the \$40 million milestone payment from PRF, AVANT expects that cash used in operations will continue to increase in 2006 as the Company continues to develop its products in clinical trials, contracts for the manufacture of clinical materials, runs its Fall River facility at full operational status, makes license and royalty payments and advances new products into preclinical development. The expected increase in cash used would be partially offset by receipt of anticipated payments under the Company's government contracts and grants and anticipated product royalty and milestone payments.

Cash used in investing activities increased to \$5,549,954 for the first nine months of 2006 compared to \$1,350,233 for the first nine months of 2005. The increase is due to increased investment in property and equipment in 2006 primarily towards the renovations of the Needham facility and for the Fall River facility compared to 2005. AVANT expects it will continue to use cash in its investing activities as the Company expands its infrastructure at the Fall River facility and continues full-scale renovations of its Needham facility.

Net cash used in financing activities was \$161,674 for the first nine months of 2006 compared to \$101,866 for the first nine months of 2005. The increase in net cash used in financing activities is primarily due to increases in payments of long-term liabilities.

# AGGREGATE CONTRACTUAL OBLIGATIONS

The following table summarizes AVANT's contractual obligations at September 30, 2006 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		2006	2007-2009		2010-2011		Thereafter	
Contractual obligations:									
Operating lease obligations	\$ 19,718,200	\$	701,500	\$	5,626,500	\$	3,604,500	\$	9,785,700
Loan Payable*	1,488,000		23,700		404,900		247,000		812,400
Note Payable*	785,500		29,500		531,500		224,500		_
Licensing obligations	531,300		21,300		255,000		170,000		85,000
Construction contracts	4,538,500		1,534,800		3,003,700		—		_
Total contractual obligations	\$ 27,061,500	\$	2,310,800	\$	9,821,600	\$	4,246,000	\$	10,683,100
Commercial commitments:									
Clinical development	\$ 425,900	\$	270,800	\$	155,100	\$		\$	_
Manufacturing development	1,435,000		1,045,500		389,500				
Total commercial commitments	\$ 1,860,900	\$	1,316,300	\$	544,600	\$	_	\$	

includes interest obligations

AVANT owns financial instruments that are sensitive to market risk as part of its investment portfolio. The Company's 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. 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, 2006 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 (the "Exchange Act"), as of September 30, 2006, AVANT carried out an evaluation under the supervision and with the participation of its management, including its Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of its disclosure controls and procedures as of the period covered by this report. In designing and evaluating AVANT's disclosure controls and procedures, AVANT and its 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 AVANT's management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. Based upon that evaluation, AVANT's Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2006, as a result of the material weakness discussed below, its disclosure controls and procedures were not effective to ensure that information required to be disclosed by AVANT in the reports it files or submits under the Exchange Act is recorded, processed, summarized, accumulated, communicated and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. AVANT will continue to review and document its 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 its disclosure controls and procedures evolve with its business.

# Changes in Internal Control Over Financial Reporting.

Management has determined that the Company did not maintain effective controls over the completeness and accuracy of the recognition of revenue deferred pursuant to an agreement with Paul Royalty Fund ("PRF") with respect to the sale of an interest in future net royalties from GlaxoSmithKline ("GSK"), certain of which should have been recognized upon receipt of a milestone payment from GSK in the first quarter of 2006. Notwithstanding that management had correctly determined the accounting treatment for the PRF transaction, an operational failure in internal control occurred in that revenue recognition was not triggered upon receipt of the milestone payment. Therefore, recognition of previously deferred royalty revenue was not completely and accurately recorded in the proper period in accordance with accounting principles generally accepted in the United States. This was identified as a deficiency in internal control in the first quarter of 2006 which constitutes a "material weakness." A material weakness is a control deficiency, or combination of control deficiencies that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. This control deficiency resulted in an audit adjustment to the unaudited interim consolidated financial statements for the quarter ended March 31, 2006 affecting deferred revenue and product royalties.

Management is in the process of reviewing and, as necessary, revising its policies and procedures with respect to its controls over the accounting for deferred royalty revenue to ensure that all reasonable steps will be taken to correct this material weakness. As part of this process, management expects to further train the Company's accounting personnel, add additional revenue recognition review and approval controls, and possibly add staff to facilitate a more timely completion of

28

such internal controls. The deficiency will not be considered remediated until the new internal controls are operational for a period of time and are tested, and management has concluded that the controls are operating effectively. Until it is remediated, the identified control deficiency could result in a misstatement in the deferred revenue and product royalties balances that would not be prevented or detected.

In the second quarter of 2006, the Company implemented changes in its internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to address the material weakness noted in the prior quarter. In the third quarter of 2006, other than the item disclosed above, there were no significant changes in the Company's controls and procedures.

29

# PART II - OTHER INFORMATION

# Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2005, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing the Company. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

- 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

Dated: November 9, 2006

Dated: November 9, 2006

30

# 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:

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

/s/ AVERY W. CATLIN

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

31

# 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

# 32

#### **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;
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2006



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

/s/ UNA S. RYAN

#### **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;
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2006

By: Name: Title:

/s/ AVERY W. CATLIN

Avery W. Catlin Senior Vice President and Chief Financial Officer The undersigned officers of AVANT Immunotherapeutics, Inc. (the "Company") hereby certify to their knowledge and in their respective capacities 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 9, 2006

Date: November 9, 2006

By:	/s/ UNA S. RYAN
Name:	Una S. Ryan, Ph.D.
Title:	President and Chief Executive Officer
By:	/s/ AVERY W. CATLIN
Name:	Avery W. Catlin
Title:	Senior Vice President and

Chief Financial Officer