## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

## **FORM 10-Q**

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

For the quarterly period ended March 31, 2002

OR

o 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

(Address of principal executive offices)

02494-2725

(Zip Code)

(781) 433-0771

(Registrant's telephone number, including area code)

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

State the number of shares outstanding of each of the registrant's classes of common equity, as of the latest practicable date:

Class Shares Outstanding as of May 8, 2002
Common Stock, \$.001 par value 60,458,397

#### AVANT IMMUNOTHERAPEUTICS, INC.

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#### PART I — FINANCIAL INFORMATION

#### **Item 1. Financial Statements**

# AVANT IMMUNOTHERAPEUTICS, INC. CONSOLIDATED BALANCE SHEET March 31, 2002 and December 31, 2001

	 March 31, 2002 (unaudited)	 December 31, 2001
ASSETS	(unauditeu)	
Current Assets:		
Cash and Cash Equivalents	\$ 37,054,200	\$ 42,665,900
Accounts Receivable	227,500	267,200
Inventories	59,400	71,500
Prepaid Expenses and Other Current Assets	 421,200	 338,800
Total Current Assets	 37,762,300	 43,343,400
Property and Equipment, Net	1,029,000	987,800
Intangible and Other Assets	7,897,800	8,117,200
Goodwill	1,036,300	 1,036,300
Total Assets	\$ 47,725,400	\$ 53,484,700
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 258,400	\$ 1,129,500
Accrued Expenses	3,120,200	2,732,600
Current Portion Deferred Revenue	 1,648,000	 1,660,400
Total Current Liabilities	 5,026,600	 5,522,500
Long-Term Deferred Revenue	2,308,500	2,693,400
Stockholders' Equity:		
Common Stock, \$.001 Par Value; 100,000,000 Shares Authorized; 60,458,400 Issued and		
Outstanding at March 31, 2002 and 60,449,100 Issued and Outstanding at December 31, 2001	60,500	60,400
Additional Paid-In Capital	223,316,800	223,281,800
Accumulated Deficit	 (182,987,000)	(178,073,400)
Total Stockholders' Equity	 40,390,300	45,268,800
Total Liabilities and Stockholders' Equity	\$ 47,725,400	\$ 53,484,700

See accompanying notes to unaudited consolidated financial statements

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#### AVANT IMMUNOTHERAPEUTICS, INC. CONSOLIDATED STATEMENT OF OPERATIONS For the Three Months Ended March 31, 2002 and 2001 (Unaudited)

	 March 31, 2002	March 31, 2001	
REVENUE:			
Product Development and Licensing Agreements	\$ 585,300	\$	737,700
Product Sales	105,600		121,300
Total Revenue	690,900		859,000
OPERATING EXPENSE:			
Research and Development	4,409,600		3,976,600
Selling, General and Administrative	1,185,900		1,214,300
Cost of Product Sales	13,700		10,100
Amortization of Acquired Intangible Assets	198,800		198,800
Amortization of Goodwill	3/4		145,200
Total Operating Expense	 5,808,000		5,545,000

Operating Loss	(5,117,100)	(4,686,000)
Investment Income, Net	 203,500	 682,400
Net Loss	\$ (4,913,600)	\$ (4,003,600)
Basic and Diluted Net Loss Per Common Share	\$ (0.08)	\$ (0.07)
Weighted Average Common Shares Outstanding	 60,457,400	57,252,200

See accompanying notes to unaudited consolidated financial statements

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#### AVANT IMMUNOTHERAPEUTICS, INC. CONSOLIDATED STATEMENT OF CASH FLOWS For the Three Months Ended March 31, 2002 and 2001 (Unaudited)

		March 31, 2002		March 31, 2001	
Cash Flows from Operating Activities:					
Net Loss	\$	(4,913,600)	\$	(4,003,600)	
Adjustments to Reconcile Net Loss to Net Cash					
Used in Operating Activities:					
Depreciation and Amortization		429,300		544,400	
Write-off of Capitalized Patent Costs		3/4		22,400	
Changes in Assets and Liabilities:					
Accounts Receivable		39,700		(21,500)	
Inventories		12,100		8,100	
Prepaid Expenses and Other Current Assets		(82,400)		(92,400)	
Increase in Other Assets		(13,400)		3/4	
Accounts Payable and Accrued Expenses		(483,500)		(1,422,500)	
Deferred Revenue		(397,300)		(301,500)	
Lease Receivable		3/4		72,000	
Lease Payable		3/4		(74,900)	
Net Cash Used in Operating Activities		(5,409,100)		(5,269,500)	
Cash Flows from Investing Activities:					
Acquisition of Property and Equipment		(185,200)		(66,900)	
Increase in Patents and Licenses		(52,500)		(22,700)	
Net Cash Used in Investing Activities		(237,700)		(89,600)	
Cash Flows from Financing Activities:					
Proceeds from Exercise of Stock Options and Warrants		35,100		287,800	
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Net Cash Provided by Financing Activities		35,100		287,800	
Decrease in Cash and Cash Equivalents		(5,611,700)		(5,071,300)	
Cash and Cash Equivalents at Beginning of Period		42,665,900		50,177,000	
Cash and Cash Equivalents at End of Period	\$	37,054,200	\$	45,105,700	
Cash and Cash Equivalents at End of Lettod	Ψ	37,034,200	Ψ	75,105,700	

See accompanying notes to unaudited consolidated financial statements

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#### AVANT IMMUNOTHERAPEUTICS, INC. Notes to Consolidated Financial Statements March 31, 2002

#### (1) Nature of Business

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

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

#### (2) <u>Interim Financial Statements</u>

The accompanying unaudited consolidated financial statements for the three months ended March 31, 2002 and 2001 include the consolidated accounts of AVANT, and have been prepared in accordance with generally accepted accounting principles and with the instructions to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, the information contained herein reflects all adjustments, consisting solely of normal recurring adjustments, that are necessary to present fairly the financial positions at March 31, 2002, the results of operations for the quarters ended March 31, 2002 and 2001, and the cash flows for the three months ended March 31, 2002 and 2001. The results of operations for the quarter ended March 31, 2002 are not necessarily indicative of results for any future interim period or for the full year.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted, although we believe that the disclosures included are adequate to make the information presented not misleading. The unaudited consolidated financial statements and the notes included herein should be read in conjunction with footnotes contained in AVANT's Annual Report on Form 10-K for the year ended December 31, 2001.

#### (3) Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board issued FAS 142, Goodwill and Other Intangible Assets. Under FAS 142, goodwill and intangible assets with indefinite lives are no longer amortized but are reviewed at least annually for impairment. The amortization provisions of FAS 142 apply to goodwill and intangible assets acquired after June 30, 2001. With respect to goodwill and intangible assets acquired prior to July 1, 2001, AVANT was required to adopt FAS 142 effective January 1, 2002. Application of the non-amortization provisions of FAS 142 for goodwill resulted in an increase in operating income of approximately \$145,200 in the first quarter of 2002. For the quarter ended March 31, 2001, we recorded amortization of goodwill of approximately \$1,036,300. Pursuant to FAS 142, we performed an annual test of goodwill for impairment during the quarter and concluded that no impairment was anticipated.

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#### (4) Inventories

Inventories are stated at the lower of cost or market. Inventories consist of finished products at March 31, 2002 and December 31, 2001. Cost is determined using the first-in, first-out (FIFO) method.

#### (5) Property and Equipment

Property and equipment includes the following:

	March 31, 2002			December 31, 2001		
Laboratory Equipment	\$	2,250,900	\$	2,235,200		
Office Furniture and Equipment		1,521,300		1,504,700		
Leasehold Improvements		1,359,200		1,206,300		
Property and Equipment, Total		5,131,400		4,946,200		
Less Accumulated Depreciation and Amortization		(4,102,400)		(3,958,400)		
	\$	1,029,000	\$	987,800		
	\$	(4,102,400)	\$	(3,958,400)		

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

Intangible and other assets include the following:

	 March 31, 2002	December 31, 2001	
Capitalized Patent Costs	\$ 2,523,200	\$ 2,470,700	
Accumulated Amortization	 (1,263,900)	(1,177,300)	
Capitalized Patent Costs, Net	1,259,300	1,293,400	
Acquired Intangible Assets:			
Collaborative Relationships	1,090,000	1,090,000	
Core Technology	1,786,900	1,786,900	
Developed Technology	3,263,100	3,263,100	
Strategic Partner Agreement	2,563,900	2,563,900	
Accumulated Amortization	 (2,150,100)	(1,951,400)	
Acquired Intangible Assets, Net	6,553,800	6,752,500	
Other Non Current Assets	84,700	71,300	
	\$ 7,897,800	\$ 8,117,200	

Consistent with SFAS 128, basic earnings (loss) per share amounts are based on the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share amounts are based on the weighted average number of shares of common stock and the potential common stock outstanding during the period. We have excluded all of the potential common stock shares from the calculation of diluted weighted average share amounts for the three-month periods ended March 31, 2002 and 2001 as its inclusion would have been anti-dilutive. A total of 5,117,700 and 4,804,500 stock options and warrants were excluded from the computation of weighted average common shares as of March 31, 2002 and 2001, respectively, as they were anti-dilutive

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Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995: Statements contained in the following, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations, that are not historical facts may be forward-looking statements that are subject to a variety of risks and uncertainties. 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: (i) our ability to successfully complete product research and development, including pre-clinical and clinical studies, and commercialization; (ii) our ability to obtain substantial additional funding; (iii) our ability to obtain required governmental approvals; (iv) our ability to attract manufacturing, sales, distribution and marketing partners and other strategic alliances; and (v) our ability to develop and commercialize our products before our competitors.

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

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

#### **OVERVIEW**

We are engaged in the discovery, development and commercialization of products that harness the human immune response to prevent and treat disease. Our products derive from a broad set of complementary technologies with the ability to enable the creation and delivery of preventative and therapeutic vaccines. We are using these technologies to develop vaccines and immunotherapeutics that prevent or treat disease caused by infectious organisms, and drugs and treatment vaccines that modify undesirable activity by the body's own proteins or cells. We develop and commercialize products on a proprietary basis and in collaboration with established pharmaceutical partners and other collaborators, including Novartis Pharma AG, GlaxoSmithKline plc, Pfizer Inc, and DynPort Vaccine Company LLC.

#### **ACQUISITIONS**

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

As of the date of the acquisition, Megan was engaged in three significant research and development projects. The value of IPR&D was determined by estimating the costs to develop the purchased in-process technology into commercially viable products, estimating the net cash flows from such projects and discounting the net cash flows back to their present values. The probability of success and discount rates in each project take into account the uncertainty surrounding the successful development and commercialization of the purchased in-process technology. The resulting net cash flows for these projects were based on our best estimates of revenue, cost of sales, research and development costs, selling, general and administrative costs, and income taxes for each project, and the net cash flows reflect assumptions that would be used by market participants. As of March 31, 2002, management's estimates have not materially changed.

Substantial additional research and development will be required prior to reaching technological feasibility on any of these products. In addition, each product needs to successfully complete a series of clinical trials and to receive USDA or other regulatory approval prior to commercialization. We are also dependent upon the activities of our collaborators in developing and marketing our products. There can be

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no assurance that these projects will ever reach feasibility or develop into products that can be marketed profitably, nor can there be assurance that AVANT and our collaborators will be able to develop and commercialize these products before our competitors. If these products are not successfully developed and do not become commercially viable, our financial condition and results of operations could be materially adversely affected.

Virus Research Institute, Inc.: On August 21, 1998, AVANT acquired Virus Research Institute, Inc. ("VRI"), a company engaged in the discovery and development of systems for the delivery of vaccines and immunotherapeutics, and novel vaccines for adults and children. In connection with the acquisition, we recorded a charge of \$44,630,000 for acquired IPR&D, which represented purchased in-process technology which had not yet reached technological feasibility and had no alternative future use. As of March 31, 2002, none of the acquired research and development projects had reached technical feasibility.

#### RECENT DEVELOPMENTS

Travelers' Vaccines: AVANT has assembled a technology portfolio for the development of single-dose, oral vaccines aimed at providing rapid protection from five of the most important causes of severe diarrhea diseases. We are developing a single dose, oral cholera vaccine using a live, genetically attenuated cholera strain. Based on this technology, developed in academia, we have developed the vaccine through early clinical trials. In May 2001, AVANT announced results of a Phase IIb clinical trial performed and funded by the Walter Reed Army Institute of Research ("WRAIR") and the National Institutes of Health ("NIH") in vaccinated individuals challenged with live, virulent cholera. Results of this study demonstrated the ability of AVANT's vaccine candidate, CholeraGarde™, to provide complete protection against the primary endpoint, moderate and severe diarrhea. AVANT plans to conduct a small dose ranging program prior to initiating pivotal Phase III clinical trials with CholeraGarde™ during the second half of 2002.

During the quarter, AVANT announced the signing of a clinical research agreement with the International Vaccine Institute ("IVI") aimed at conducting clinical trials of AVANT's CholeraGarde<sup>TM</sup> vaccine in Bangladesh. Under the direction of John D. Clemens, M.D., IVI plans to begin conducting clinical trials of our cholera vaccine in Bangladesh during 2002. These trials will provide important safety and immunogenicity data on our cholera vaccine in endemic areas.

Development of a safe, effective cholera vaccine is the first step in establishing AVANT's travelers' vaccine franchise. During 2002, we plan to initiate Phase II clinical studies aimed at demonstrating clinical proof-of-principle for the second product in our vaccine portfolio, Ty800. AVANT has designed the Ty800 vaccine to offer rapid, single-dose protection against *Salmonella typhi*, the cause of typhoid fever. With the acquisition of Megan, AVANT gained access to technologies for developing vaccines against *Shigella*, *Campylobacter* and enterotoxigenic *E. coli*, three additional causes of serious diarrheal diseases worldwide. These three vaccine programs are currently in pre-clinical development.

AVANT's single dose, oral vaccine technology is currently addressed to serious bacterial diseases. However, the attenuated live bacteria used to create these vaccines also can serve as vectors for the development of vaccines against other bacterial and viral diseases. We are exploring further opportunities to use this technology to create potent, single-dose oral vaccines that rapidly protect military personnel and civilians against bacterial and viral agents used in biowarfare or terrorist activities.

Cholesterol Treatment Vaccine: We are developing an immunotherapeutic vaccine against endogenous cholesteryl ester transfer protein ("CETP"), which may be useful in reducing risks associated with atherosclerosis. CETP is a key intermediary in the balance of HDL (high-density lipoprotein) and LDL. We are developing this vaccine (CETi-1) to stimulate an immune response against CETP, which we believe may improve the ratio of HDL to LDL cholesterol and reduce the progression of atherosclerosis. We have conducted preliminary studies of rabbits, which have demonstrated the ability of CETi-1 vaccine to elevate HDL and reduce the development of blood vessel lesions. In September 1999, we initiated a double-blind placebo controlled, Phase I clinical trial of our CETi-1 vaccine in adult volunteers. The object

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of the study was to demonstrate the safety of single administrations of the vaccine at four different dosage strengths and results were announced in January 2001.

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

These data were extremely helpful in moving the program forward to a placebo controlled Phase II study, which was initiated in August 2001, in approximately 200 patients with low levels of HDL cholesterol. The objectives of the study are to evaluate the safety, immunogenicity and dose-response relationship of the CETi-1 product in patients who receive an initial immunization followed by boosters. The primary endpoint is the change in HDL cholesterol measured after the six-month booster. Results are expected from the trial during 2003. As clinical data become available, we plan to seek a corporate partner to complete development and to commercialize the CETi-1 vaccine.

Rotavirus Vaccine: Rotavirus is a major cause of diarrhea and vomiting in infants and children. No vaccine against rotavirus is currently on the market. In 1997, we licensed our oral rotavirus vaccine to Glaxo. In 1999, after our Phase II study demonstrated 89% protection in a study involving 215 infants, Glaxo paid us an additional license fee and assumed full responsibility for funding and performing all remaining clinical development. Glaxo has initiated Phase I/II bridging studies in Europe using its newly manufactured rotavirus vaccine, called Rotarix<sup>TM</sup>. Glaxo is now planning to initiate final stage global clinical development of the vaccine. Assuming product development and commercialization continues satisfactorily, we may receive additional milestone payments of up to \$8.5 million upon the achievement of specified milestones. In addition, we will be entitled to royalties based on net sales of Rotarix<sup>TM</sup>.

Complement Inhibitors: In 1997, we entered into an agreement with Novartis relating to the development of our complement inhibitor, TP10, for use in xenotransplantation (animal organs into humans) and allotransplantation (human organs into humans). The decision to license TP10 resulted in a \$6 million equity investment and license payment by Novartis which was received by AVANT in January 2000. Under the agreement, we may receive additional milestone payments of up to \$14 million upon attainment of certain development and regulatory goals. We will also be entitled to royalties on product sales under the agreement.

We elected to independently develop and commercialize TP10 for pediatric and adult cardiac surgery. In 2000, we completed an open-label, Phase I/II trial of TP10 in infants undergoing cardiac surgery for congenital heart defects. In early 2001, AVANT initiated two Phase IIb studies of TP10 in pediatric cardiac surgery utilizing cardiopulmonary bypass.

In November 2000, AVANT initiated a placebo-controlled Phase II trial in adult patients undergoing high-risk cardiac surgery utilizing cardiopulmonary bypass. In February 2002, AVANT announced that the results of the trial showed that TP10 failed to meet the trial's primary endpoint. The results showed that there were no clinically important differences between placebo and any of the four dose groups. TP10 was well tolerated with no apparent differences in the safety profiles of the treatment groups.

Based on the outcomes of the adult TP10 trial, AVANT is presently in the process of closing out the two Phase IIb studies of TP10 in pediatric cardiac surgery utilizing cardiopulmonary bypass. AVANT is further evaluating the future of its complement inhibitor program but no longer plans to advance clinical development on its own or to invest a significant amount of its own resources into the development of this

#### TECHNOLOGY LICENSING

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

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

Formation of Parallel Solutions: During October 2001, AVANT contributed its polyphosphazene polymer adjuvant business (the "PCPP business"), including Adjumer® and Micromer®, into a newly formed, privately held company, Parallel Solutions, Inc. ("Parallel"), in exchange for a non-controlling minority ownership position in Parallel. AVANT believes that Parallel's plans to expand the PCPP business beyond vaccine adjuvants, and indeed beyond human therapeutics, offer greater opportunities to create value. This transaction allows AVANT to further leverage this technology with the potential for significant upside benefits as a shareholder of Parallel, while divesting its obligations for manufacturing PCPP and the burden of funding the PCPP business. In connection with this transaction, AVANT has assigned all of its rights and obligations under the Aventis license agreements to Parallel. AVANT has no future funding commitments or other obligations to Parallel and has neither a role in the management of Parallel nor representation on the Parallel board of directors.

#### RESULTS OF OPERATIONS

Three Month Period Ended March 31, 2002 as Compared With the Three Month Period Ended March 31, 2001

AVANT reported consolidated net loss of \$4,913,600, or \$.08 per share, for the first quarter ended March 31, 2002, compared with a net loss of \$4,003,600, or \$.07 per share, for the first quarter ended March 31, 2001. The weighted average common shares outstanding used to calculate net loss per common share was 60,457,400 in 2002 and 57,252,200 in 2001.

Revenue: Total revenue decreased \$168,100, or 19.6%, to \$690,900 for the first quarter of 2002 compared to \$859,000 for the first quarter of 2001.

Product development and licensing revenue decreased \$152,400, or 20.7%, to \$585,300 in 2002 from \$737,700 in 2001. In 2002, product development and licensing revenue consisted primarily of \$384,900 for the amortization of nonrefundable license fees from Novartis and Pfizer, \$125,000 in funded research from Pfizer, \$37,500 in license fee and milestone payments from DynPort and \$37,900 received in connection with government grants. In 2001, we recognized \$384,900 in the amortization of nonrefundable license fees from Novartis and Pfizer, \$164,000 from Innogenetics, Inc. in connection with its acquisition of the TRAx business in 1999, \$167,000 in funded research and development from Pfizer and \$21,800 received in connection with a government grant.

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Product sales for the first quarter of 2002 totaled \$105,600 compared to \$121,300 for 2001 and were derived from sales of our Megan®Vac 1 product, a vaccine for use in chickens for protection against multiple strains of *Salmonella* bacteria, which we acquired in connection with our acquisition of Megan.

*Operating Expense:* Total operating expense increased \$263,000, or 4.7%, to \$5,808,000 for the first quarter of 2001 compared to \$5,545,000 for the first quarter of 2001. The increase in total operating expense for 2002 compared to 2001 is primarily due to increased personnel and related expenses, clinical materials costs incurred in connection with AVANT's travelers' vaccines programs and increased consultancy costs, offset in part by decreased clinical trials costs and legal expenses.

Research and development expense increased \$432,900, or 10.9%, to \$4,409,600 in 2002 from \$3,976,700 in 2001. The increase in 2002 compared to 2001 is primarily due to an increase in expense associated with the manufacture of clinical materials for the CholeraGarde™ and Ty800 travelers' vaccines programs, increased personnel and related expenses and increased consultancy costs, off set in part by reduced costs associated with conducting clinical trials of TP10.

Selling, general and administrative expense decreased \$28,400, or 2.3%, to \$1,185,900 in 2002 compared to \$1,214,300 in 2001. The decrease in expense in 2002 compared to 2001 is primarily attributed to a reduction in legal expenses and a decrease in selling and marketing expense in 2002, offset in part by an increase in personnel and related costs and consultancy costs.

Amortization expense of goodwill decreased \$145,200 in 2002 from 2001 as a result of the adoption of FAS 142 under which goodwill and intangible assets with indefinite lives are no longer amortized but are reviewed at least annually for impairment.

*Investment Income, Net:* Interest income decreased \$478,900, or 70.2%, to \$203,500 for the first quarter of 2002 compared to \$682,400 for the first quarter of 2001. The decrease is primarily due to significantly lower interest rates and lower average cash balances during the first quarter of 2002 compared to the first quarter of 2001.

#### LIQUIDITY AND CAPITAL RESOURCES

AVANT ended the first quarter of 2002 with cash and cash equivalents of \$37,054,200 compared to cash and cash equivalents of \$42,665,900 at December 31, 2001.

Net cash used in operating activities increased to \$5,409,100 for the first three months of 2002 compared to \$5,269,500 for the first three months of 2001. The increase is primarily attributed to the increase in net loss incurred in 2002 compared to 2001.

Net cash used in investing activities increased to \$237,700 for the first three months of 2002 compared to \$89,600 for the first three months of 2001. The increase is primarily due to increased investment in property and equipment, particularly leasehold improvements, in 2002 compared to 2001.

Net cash provided by financing activities decreased to \$35,100 for the first three months of 2002 compared to \$287,800 for the first three months of 2001. The decrease is primarily due to a decrease in proceeds from the exercise of stock options and warrants.

AVANT believes that cash inflows from existing collaborations, interest income on invested funds and our current cash and cash equivalents will be sufficient to meet estimated working capital requirements and fund operations beyond December 31, 2002. The working capital requirements of AVANT are dependent on several factors including, but not limited to, the costs associated with research and development programs, preclinical and clinical studies and the scope of collaborative arrangements. During 2002, we expect to take steps to raise additional capital including, but not limited to, the licensing of technology programs with existing or new collaborative partners, possible business combinations, or the issuance of common stock via private placement and public offering. There can be no assurance that such efforts will be successful.

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

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

We do not utilize derivative financial instruments. The carrying amounts reflected in the consolidated balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximates fair value at March 31, 2002 and December 31, 2001 due to the short-term maturities of these instruments.

#### PART II — OTHER INFORMATION

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

(a) Exhibits

None.

Exhibit 3.1 Third Certificate of Amendment of Third Restated Certificate of Incorporation of AVANT Immunotherapeutics, Inc.\*

(b) Reports on Form 8-K

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#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

#### AVANT IMMUNOTHERAPEUTICS, INC.

BY:

Dated: May 8, 2002

/s/ Una S. Ryan

Una S. Ryan, Ph. D.

President and Chief Executive Officer (Principal Executive Officer)

Dated: May 8, 2002

/s/ Avery W. Catlin

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

<sup>\*</sup> Filed herewith.

# THIRD CERTIFICATE OF AMENDMENT OF THIRD RESTATED CERTIFICATE OF INCORPORATION OF AVANT IMMUNOTHERAPEUTICS, INC.

AVANT Immunotherapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), does hereby certify that:

FIRST: The first paragraph of Article FOURTH of the Third Restated Certificate of Incorporation, as amended, of the Corporation is hereby amended to read in its entirety as follows:

"FOURTH: The total number of shares of capital stock which the Corporation shall have the authority to issue is 103,000,000 shares of which (i) 100,000,000 shares shall be common stock, par value \$.001 per share (the "Common Stock") and (ii) 3,000,000 shares shall be preferred stock, par value \$.01 per share, all of which shall be designated Class C Preferred Stock ("Class C Stock") of which 350,000 shall be designated Series C-1 Junior Participating Cumulative Preferred Stock (the "Series C-1 Preferred Stock")."

SECOND: The amendment of the Third Restated Certificate of Incorporation set forth herein was duly authorized by resolution of the Corporation's Board of Directors and was considered and duly authorized by the stockholders of the Corporation at the Annual Meeting of Stockholders of the Corporation duly called and held upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware.

THIRD: Such amendment was duly adopted in accordance with the applicable provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the undersigned has signed this Third Certificate of Amendment of the Third Restated Certificate of Incorporation of the Corporation, this 22<sup>nd</sup> day of April, 2002, and affirmed that the statements contained herein are true.

AVANT Immunotherapeutics, Inc.

By: /s/ Una S. Ryan

Name: Una S. Ryan

Title: President and Chief Executive Officer

ATTEST:

/s/ Avery W. Catlin

Name: Avery W. Catlin
Title: Chief Financial Officer