# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

# FORM 10-Q

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

**For the quarterly period ended September 30, 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** | **No. 13-3191702** |
|---|---|
| (State of Incorporation) | (I.R.S. Employer Identification No.) |

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

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

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

As of November 6, 2002, 60,464,897 shares of common stock, $.001 par value per share, were outstanding.

**AVANT IMMUNOTHERAPEUTICS, INC.**

**FORM 10-Q**

**Quarter Ended September 30, 2002**

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**PART I — FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**AVANT IMMUNOTHERAPEUTICS, INC.**
**CONSOLIDATED BALANCE SHEET**
**September 30, 2002 and December 31, 2001**

| | September 30, 2002 (unaudited) | December 31, 2001 |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and Cash Equivalents | $ 26,314,000 | $ 42,665,900 |
| Accounts Receivable | 2,124,300 | 267,200 |
| Inventories | ¾ | 71,500 |
| Prepaid Expenses and Other Current Assets | 706,300 | 338,800 |
| Total Current Assets | 29,144,600 | 43,343,400 |
| Property and Equipment, Net | 1,038,200 | 987,800 |
| Intangible and Other Assets | 7,470,800 | 8,117,200 |
| Goodwill | 1,036,300 | 1,036,300 |
| Total Assets | $ 38,689,900 | $ 53,484,700 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts Payable | $ 496,800 | $ 1,129,500 |
| Accrued Expenses | 2,118,600 | 2,732,600 |
| Current Portion Deferred Revenue | 1,007,600 | 1,660,400 |
| Total Current Liabilities | 3,623,000 | 5,522,500 |
| Long-Term Deferred Revenue | 154,000 | 2,693,400 |
| Stockholders' Equity: | | |
| Common Stock, $.001 Par Value: 100,000,000 Shares Authorized; 60,458,400 Issued and Outstanding at September 30, 2002 and 60,449,100 Issued and Outstanding at December 31, 2001 | 60,500 | 60,400 |
| Additional Paid-In Capital | 223,323,000 | 223,281,800 |
| Less: 40,700 Common Treasury Shares at Cost at September 30, 2002 | (43,100) | ¾ |
| Accumulated Deficit | (188,427,500) | (178,073,400) |
| Total Stockholders' Equity | 34,912,900 | 45,268,800 |
| Total Liabilities and Stockholders' Equity | $ 38,689,900 | $ 53,484,700 |

*See accompanying notes to unaudited consolidated financial statements*



**AVANT IMMUNOTHERAPEUTICS, INC.**
**CONSOLIDATED STATEMENT OF OPERATIONS**
**For the Three Months Ended September 30, 2002 and 2001**
**(Unaudited)**

| | September 30, 2002 | September 30, 2001 |
|---|---|---|
| **REVENUE:** | | |
| Product Development and Licensing Agreements | $ 4,493,900 | $ 663,800 |
| Product Sales | 66,500 | 61,700 |
| Total Revenue | 4,560,400 | 725,500 |

| | | |
|---|---|---|
| **OPERATING EXPENSE:** | | |
| Research and Development | 3,423,200 | 5,633,100 |
| Selling, General and Administrative | 1,325,600 | 1,321,700 |
| Cost of Product Sales | 10,300 | 8,400 |
| Amortization of Acquired Intangible Assets | 198,800 | 198,800 |
| Amortization of Goodwill | ¾ | 145,200 |
| Total Operating Expense | 4,957,900 | 7,307,200 |
| Operating Loss | (397,500) | (6,581,700) |
| Investment Income, Net | 121,300 | 357,700 |
| Net Loss | $ (276,200) | $ (6,224,000) |
| Basic and Diluted Net Loss Per Common Share | $ (0.01) | $ (0.11) |
| Weighted Average Common Shares Outstanding | 60,464,900 | 57,379,700 |

*See accompanying notes to unaudited consolidated financial statements*



**AVANT IMMUNOTHERAPEUTICS, INC.**
**CONSOLIDATED STATEMENT OF OPERATIONS**
**For the Nine Months Ended September 30, 2002 and 2001**
**(Unaudited)**

| | September 30, 2002 | September 30, 2001 |
|---|---|---|
| **REVENUE:** | | |
| Product Development and Licensing Agreements | $ 5,601,600 | $ 2,133,100 |
| Product Sales | 292,400 | 277,100 |
| Total Revenue | 5,894,000 | 2,410,200 |
| **OPERATING EXPENSE:** | | |
| Research and Development | 11,899,200 | 15,135,400 |
| Selling, General and Administrative | 4,199,000 | 3,648,700 |
| Cost of Product Sales | 41,000 | 26,700 |
| Amortization of Acquired Intangible Assets | 596,400 | 596,400 |
| Amortization of Goodwill | ¾ | 435,600 |
| Total Operating Expense | 16,735,600 | 19,842,800 |
| Operating Loss | (10,841,600) | (17,432,600) |
| Investment Income, Net | 487,500 | 1,535,000 |
| Net Loss | $ (10,354,100) | $ (15,897,600) |
| Basic and Diluted Net Loss Per Common Share | $ (0.17) | $ (0.28) |
| Weighted Average Common Shares Outstanding | 60,460,300 | 57,329,600 |

*See accompanying notes to unaudited consolidated financial statements*



**AVANT IMMUNOTHERAPEUTICS, INC.**
**CONSOLIDATED STATEMENT OF CASH FLOWS**
**For the Nine Months Ended September 30, 2002 and 2001**
**(Unaudited)**

| | September 30, 2002 | September 30, 2001 |
|---|---|---|
| **Cash Flows from Operating Activities:** | | |

| | | |
|---|---|---|
| Net Loss | $ (10,354,100) | $ (15,897,600) |
| Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities: | | |
| Depreciation and Amortization | 1,227,300 | 1,654,300 |
| Write-off of Capitalized Patent Costs | ¾ | 22,400 |
| Changes in Assets and Liabilities: | | |
| Accounts Receivable | (1,857,100) | (8,000) |
| Inventories | 71,500 | (19,700) |
| Prepaid Expenses and Other Current Assets | (367,500) | 158,200 |
| Increase in Other Non-Current Assets | (13,400) | ¾ |
| Accounts Payable and Accrued Expenses | (1,246,700) | (296,900) |
| Deferred Revenue | (3,192,300) | (1,071,300) |
| Lease Receivable | ¾ | 323,800 |
| Lease Payable | ¾ | (224,700) |
| Net Cash Used in Operating Activities | (15,732,300) | (15,359,500) |
| **Cash Flows from Investing Activities:** | | |
| Acquisition of Property and Equipment | (392,000) | (456,300) |
| Increase in Patents and Licenses | (225,700) | (129,800) |
| Net Cash Used in Investing Activities | (617,700) | (586,100) |
| **Cash Flows from Financing Activities:** | | |
| Proceeds from Exercise of Stock Options and Warrants | 41,200 | 505,500 |
| Purchases of Treasury Stock | (43,100) | ¾ |
| Net Cash (Used In) Provided by Financing Activities | (1,900) | 505,500 |
| Decrease in Cash and Cash Equivalents | (16,351,900) | (15,440,100) |
| Cash and Cash Equivalents at Beginning of Period | 42,665,900 | 50,177,000 |
| Cash and Cash Equivalents at End of Period | $ 26,314,000 | $ 34,736,900 |

*See accompanying notes to unaudited consolidated financial statements*



**AVANT IMMUNOTHERAPEUTICS, INC.**
**Notes to Consolidated Financial Statements**
**September 30, 2002**

## (1) Nature of Business

AVANT Immunotherapeutics, Inc. ("AVANT" or the "Company") is engaged in the discovery, development and commercialization of products that harness the human and animal immune systems 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 and people in endemic regions 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 and its wholly owned subsidiary, Megan Health, Inc. All intercompany transactions have been eliminated.

## (2) Interim Financial Statements

The accompanying unaudited consolidated financial statements for the three months and nine months ended September 30, 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 September 30, 2002, the results of operations for the quarters and nine-month periods ended September 30, 2002 and 2001, and the cash flows for the three months and nine months ended September 30, 2002 and 2001. The results of operations for the quarter and nine-month period ended September 30, 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 the footnotes contained in AVANT's Annual Report on Form 10-K for the year ended December 31, 2001.

## (3) New Accounting Pronouncements

In July 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized at its fair market value when the liability is incurred, rather than at the date of an entity's

commitment to an exit plan. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have a material effect on the Company's financial statements.

**(4) Inventories**

Inventories are stated at the lower of cost or market. As of September 1, 2002, AVANT sold its inventories to Lohmann Animal Health International (LAHI) pursuant to a Distribution Agreement between AVANT and LAHI. Inventories consisted of finished products at December 31, 2001. Cost was determined using the first-in, first-out (FIFO) method.



**(5) Property and Equipment**

Property and equipment includes the following:

| | September 30, 2002 | December 31, 2001 |
|---|---|---|
| Laboratory Equipment | $ 2,293,200 | $ 2,235,200 |
| Office Furniture and Equipment | 1,576,100 | 1,504,700 |
| Leasehold Improvements | 1,468,800 | 1,206,300 |
| Property and Equipment, Total | 5,338,100 | 4,946,200 |
| Less Accumulated Depreciation and Amortization | (4,299,900) | (3,958,400) |
| | $ 1,038,200 | $ 987,800 |

In August 2001, we extended our lease of approximately 54,300 sq. ft. of laboratory and office space in Needham, Massachusetts through April 30, 2007. In April 2002, we leased approximately 12,400 sq. ft. of laboratory and office space in St. Louis, Missouri through March 31, 2004.

Obligations for base rent under these and other noncancelable operating leases as of September 30, 2002 are approximately as follows:

| | | |
|---|---|---|
| Year ending December 31, | 2002 (including remaining three months) | $ 1,986,300 |
| | 2003 | 2,285,000 |
| | 2004 | 2,191,300 |
| | 2005 | 2,186,900 |
| | 2006 and thereafter | 2,961,700 |
| | Total minimum lease payments | $ 11,611,200 |

Our total rent for all operating leases (including rent expense net of sublease income) was approximately $1,359,400 for the nine months ended September 30, 2002.

**(6) Goodwill, Intangible and Other Assets**

In June 2001, the Financial Accounting Standards Board issued SFAS 142, "Goodwill and Other Intangible Assets". Under SFAS 142, goodwill and intangible assets with indefinite lives are no longer amortized but are reviewed at least annually for impairment. The amortization provisions of SFAS 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 SFAS 142 and cease amortization of goodwill effective January 1, 2002.

*Goodwill:* We adopted SFAS 142 in January 2002. Prior to the adoption, the carrying amount of goodwill was approximately $1,036,300. In accordance with the provisions of SFAS 142, we reclassified our assembled workforce intangible assets of $277,800 to goodwill. AVANT has concluded that it currently has one reporting unit and has assigned the entire balance of goodwill to this reporting unit for purposes of performing a transitional impairment test as of January 1, 2002 as well as the annual impairment test as of July 1, 2002. The fair value of the reporting unit was determined using AVANT's market capitalization as of January 2, 2002 and July 1, 2002. The fair value on January 2, 2002 and July 1, 2002 exceeded the net assets of the reporting unit, including goodwill. Accordingly, we concluded that no impairment existed as of that date.



*Intangible and Other Assets:* Intangible and other assets include the following:

| | September 30, 2002 | December 31, 2001 |
|---|---|---|
| Capitalized Patent Costs | $ 2,696,500 | $ 2,470,700 |
| Accumulated Amortization | (1,466,700) | (1,177,300) |
| | | |
| Capitalized Patent Costs, Net | 1,229,800 | 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 | (2,547,700) | (1,951,400) |

| | | |
|---|---|---|
| Acquired Intangible Assets, Net | 6,156,200 | 6,752,500 |
| Other Non Current Assets | 84,800 | 71,300 |
| | $ 7,470,800 | $ 8,117,200 |

All of our intangible assets are amortized over their useful lives. Total amortization expense for intangible assets was $198,800 and $596,400 for the three-month and nine-month periods ended September 30, 2002 and $198,800 and $596,400 for the three-month and nine-month periods ended September 30, 2001.

The estimated future amortization expense of intangible assets as of September 30, 2002 for the remainder of fiscal year 2002 and the five succeeding years is as follows:

| Year ending December 31, | Estimated Amortization Expense |
|---|---|
| 2002 (remaining three months) | $ 198,800 |
| 2003 | 795,200 |
| 2004 | 795,200 |
| 2005 | 795,200 |
| 2006 | 795,200 |
| 2007 | 760,200 |

*Adjusted Net Loss:* The following table presents the impact SFAS 142 would have had on our net loss and net loss per share had the standard been in effect for the three months and nine months ended September 30, 2001:

| | Three Months Ended September 30, 2001 | | |
|---|---|---|---|
| | As Reported | Goodwill Amortization Adjustment | As Adjusted |
| Net Loss | $ (6,224,000) | $ (145,200) | $ (6,078,800) |
| Net Loss per Common Share | $ (0.11) | $ — | $ (0.11) |



| | Nine Months Ended September 30, 2001 | | |
|---|---|---|---|
| | As Reported | Goodwill Amortization Adjustment | As Adjusted |
| Net Loss | $ (15,897,600) | $ (435,600) | $ (15,462,000) |
| Net Loss per Common Share | $ (0.28) | $ (0.01) | $ (0.27) |

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

Consistent with SFAS 128, basic earnings (loss) per share amounts are based on the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share amounts are based on the weighted average number of shares of common stock and the potential common stock outstanding during the period. We have excluded all of the potential common stock shares from the calculation of diluted weighted average share amounts for the three-month and nine-month periods ended September 30, 2002 and 2001 as its inclusion would have been anti-dilutive. A total of 5,073,900 and 4,819,600 stock options and warrants were excluded from the computation of weighted average common shares as of September 30, 2002 and 2001, respectively, as they were anti-dilutive.

**(8) Share Repurchase Plan**

On August 16, 2002, the Company announced that its Board of Directors had authorized the repurchase of up to 2 million shares of the Company's common stock. The repurchased stock provides the Company with treasury shares for general corporate purposes, such as stock to be issued under employee stock option and stock purchase plans. The Company purchased 40,700 shares through September 30, 2002 at a cost of $43,100. Approximately 1,959,300 shares remain authorized for repurchase under this program at September 30, 2002.

**(9) Termination of Novartis Agreement**

In September 2002, the Company terminated its agreement on TP10 in transplantation with Novartis. The termination resulted in a $2 million fee payable by Novartis and the recognition of the remaining $2.0 million in deferred revenue related to the Novartis agreement. The Novartis-related revenue is non-recurring in nature and the deferred revenue portion represents non-cash revenue. Also pursuant to the termination agreement, Novartis is obligated to return all pre-clinical and clinical TP10 material to AVANT.



*Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995: This quarterly report on Form 10-Q includes forward-looking statements which reflect AVANT's current views with respect to future events and financial performance. These forward-looking statements are based on management's beliefs and assumptions and information currently available. The words "believe", "expect", "anticipate", "intend", "estimate", "project" and similar expressions which do not relate solely to historical matters identify forward-looking statements. You should be cautious in relying on forward-looking statements because they are subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially from those*

*expressed in any such forward-looking statements. These factors include, but are not limited to: (1) the proposed acquisition of UPT and related transactions may not be consummated on the terms currently anticipated or at all; (2) the ability to successfully complete development and commercialization of products, including the cost, timing, scope and results of pre-clinical and clinical testing; (3) the ability to successfully complete product research and further development, including animal, pre-clinical and clinical studies, and the adaptation of our attenuated vaccine technology to different infectious diseases; (4) the ability of the Company to manage multiple late stage clinical trials for a variety of product candidates; (5) the volume and profitability of product sales of Megan®Vac 1 and other future products; (6) changes in existing and potential relationships with corporate collaborators; (7) the cost, delivery and quality of clinical and commercial grade materials supplied by contract manufacturers; (8) the timing, cost and uncertainty of obtaining regulatory approvals; (9) the ability to obtain substantial additional funding; (10) the ability to develop and commercialize products before competitors; (11) the ability to retain certain members of management; and (12) other factors detailed from time to time in filings with the Securities and Exchange Commission. We expressly disclaim any responsibility to update forward-looking statements.*

**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 and animal immune responses 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 GlaxoSmithKline plc, Pfizer Inc, Lohmann Animal Health International, and DynPort Vaccine Company LLC.

**ACQUISITIONS**

*Megan Health, Inc.:* In December 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. 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 resulting net cash flows were based on our best estimates of revenue, cost of sales, research and development costs, selling, general and administrative



costs, and income taxes, and the net cash flows reflect assumptions that would be used by market participants. As of September 30, 2002, management's estimates have not materially changed.

*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 September 30, 2002, none of the acquired research and development projects had reached technical feasibility.

*Universal Preservation Technologies, Inc.:* On October 23, 2002, AVANT announced that the company had agreed in principle to acquire the technology and intellectual property portfolio of Universal Preservation Technologies, Inc. (UPT), a privately held company based in San Diego, California, and to license certain patent rights from Elan Drug Delivery Limited (a subsidiary of Elan Corporation plc). Through this transaction, AVANT will gain exclusive rights to UPT's VitriLifeÒ process for use in AVANT's oral vaccines and certain other non-injectable applications. AVANT plans to complete its acquisition of the UPT technology, patents and license agreements by year-end.

**CRITICAL ACCOUNTING POLICIES**

Our critical accounting policies are set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 to our 2001 Form 10-K. There have been no changes to these policies since December 31, 2001.

**RECENT DEVELOPMENTS**

*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 (low-density lipoprotein). We are developing this vaccine (CETi-1) to stimulate an immune response against CETP, which we believe may improve the ratio of HDL to LDL cholesterol and reduce the progression of atherosclerosis. CETi-1 is being developed for the management of patients with low levels of HDL cholesterol. We have conducted preliminary studies in 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 objective of the study was to demonstrate the safety of a single administration of the vaccine at four different dosage strengths. The 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 clinically significant 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-blind placebo controlled extension of the earlier completed CETi-1 Phase I trial in the same healthy adult volunteers receiving a second dose of the vaccine. Results from the extension study showed measurable antibody titers in all dose groups treated with study medication,

suggesting a dose-response relationship. As previously demonstrated, CETi-1 was well tolerated with no clinically significant differences between active and control groups.

These data were extremely helpful in moving the program forward to a blinded, 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. On August 1, 2002, we announced that enrollment of all patients had been completed. Results are expected from the trial



during the second half of 2003. When clinical data become available, we plan to seek a corporate partner to complete development and to commercialize the CETi-1 vaccine.

In June 2002, the United States Patent and Trademark Office issued U.S. patent 6,410,022, a key patent that underlies the CETi-1 product candidate presently under study in the Phase II clinical trial, and underpins AVANT's broad intellectual property coverage of vaccine approaches to inhibiting CETP.

*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™. 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™.

*Bacterial 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. 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. In May 2002, we initiated a Phase II dose ranging study in 120 adult volunteers to identify a dose of cholera vaccine that produces an optimal immune response combined with an optimal safety profile. On September 30, 2002, we announced that the trial had successfully established that a single, oral dose of $10^8$ cfu (*colony forming units*) produces a significant immune response and was well tolerated in vaccinated individuals. The results also confirmed that the new buffer system works well with our cholera vaccine, and the study had generated sufficient data to describe a dose-response relationship for the vaccine. Reported adverse events (diarrhea, abdominal pain, and headache) were mild and were similar in frequency amongst volunteers receiving placebo and those receiving the vaccine.

In 2001, we entered into manufacturing supply agreements with Bio Sidus S.A. of Buenos Aires, Argentina, for the manufacture of clinical grade quantities of CholeraGarde™ and Ty800, our vaccine against typhoid fever. Bio Sidus has encountered a number of delays during the technology transfer and scale-up manufacture of these vaccines. We now expect Ty800 clinical material to be delivered in early 2003 and CholeraGarde™ clinical material to be delivered during the first half of 2003. In light of the significant costs expected to be incurred when we start Phase III trials of our cholera vaccine in the U.S., as well as the manufacturing delays experienced by Bio Sidus, we are re-assessing our plans for these trials. We are also seeking alternative ways of funding these trials, including third party funding.

In February 2002, AVANT announced the signing of a clinical research agreement with the International Vaccine Institute ("IVI") aimed at conducting clinical trials of AVANT's CholeraGarde™ 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 within the next six months. 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 vaccine franchise. AVANT has designed the Ty800 vaccine to offer rapid, single-dose protection against *Salmonella typhi*, the cause of typhoid fever. We plan to initiate a Phase I in-patient safety and dose ranging clinical study aimed at demonstrating safety and immunogenicity of lyophilized Ty800 vaccine, the second product in our vaccine portfolio. This trial will be followed by a larger Phase II out-patient safety and immunogenicity study in approximately 200 adult volunteers. We are currently seeking outside sources to help fund the cost of these trials. 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 would rapidly protect military personnel and civilians against bacterial and viral agents used in biowarfare or terrorist activities. In July 2002, we received a Phase I SBIR grant from the National Institute of Allergy and Infectious Disease (NIAID) of the National Institutes of Health (NIH) to support the development of our single oral-dose bacterial vectors to immunize people against anthrax.

*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. In September 2002, AVANT and Novartis terminated the TP10 agreement pursuant to which Novartis is obligated to pay a termination fee of $2.0 million and return to AVANT all pre-clinical and clinical TP10 material.

Based on the outcomes of the adult TP10 trial in which TP10 failed to meet the trial's primary endpoint, AVANT no longer plans to advance clinical development of the complement inhibitor program on its own or to invest a significant amount of its own resources into the development of this program going forward. Instead, we plan to seek partnering arrangements to capture the value inherent in this program and its strong intellectual property. With the termination of the Novartis agreement, AVANT can now offer a worldwide license for all fields, which we believe improves the likelihood of a partnership arrangement.

**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. In September 2002, AVANT announced the appointment of Lohmann Animal Health International, a leader in the poultry industry with an extensive product line of vaccines and related products, as the exclusive distributor of its Megan Health poultry vaccines in North America.

*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.

On October 15, 2002, DynPort announced that it was entering into a Phase I clinical trial of a new injectable recombinant anthrax vaccine in approximately 70 volunteers. The vaccine candidate consists of a highly purified protein – Protective Antigen – derived from the anthrax bacterium using recombinant technology and advance production processes licensed from AVANT. DynPort hopes this vaccine will offer a safe, effective product to support the country's need for a new-generation anthrax vaccine.



*Formation of Parallel Solutions:* In 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 September 30, 2002 as Compared
With the Three-Month Period Ended September 30, 2001

AVANT reported consolidated net loss of $276,200, or $.01 per share, for the third quarter ended September 30, 2002, compared with a net loss of $6,224,000, or $.11 per share, for the third quarter ended September 30, 2001. The weighted average common shares outstanding used to calculate net loss per common share was 60,464,900 in 2002 and 57,379,700 in 2001.

*Revenue:* Total revenue increased $3,934,900 to $4,560,400 for the third quarter of 2002 compared to $725,500 for the third quarter of 2001.

Product development and licensing revenue increased $3,830,100 to $4,593,900 in 2002 from $663,800 in 2001. In 2002, product development and licensing revenue consisted primarily of $1,900,000 receivable from Novartis in net termination fees, $2,384,900 for the amortization of nonrefundable license fees from Novartis and Pfizer, $125,000 in funded research from Pfizer, $71,500 in government grants and $12,500 in license fees from DynPort. The Novartis termination fee is non-recurring in nature and the Novartis deferred revenue of approximately $2,000,000 recognized due to the termination is also non-recurring revenue. In 2001, we recognized $384,900 in the amortization of nonrefundable license fees from Novartis and Pfizer, $125,000 in funded research and development from Pfizer and $153,900 received in connection with government grants.

Product sales for the third quarter of 2002 totaled $66,500 compared to $61,700 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. In September 2002, AVANT appointed Lohmann Animal Health International as the exclusive distributor of the Megan Health poultry vaccines in North America.

*Operating Expense:* Total operating expense decreased $2,349,300, or 32.2%, to $4,957,900 for the third quarter of 2002 compared to $7,307,200 for the third quarter of 2001. The decrease in total operating expense for 2002 compared to 2001 is primarily attributed to a reduction in sponsored research spending, clinical trials costs and clinical materials costs incurred in connection with AVANT's TP10 adult and pediatric programs, offset in part by increased consultancy costs, corporate communications expenses and facility-related costs and a decrease in investment income.

Research and development expense decreased $2,209,900, or 39.2%, to $3,423,200 for the third quarter of 2002 from $5,633,100 for the third quarter of 2001. The decrease in 2002 compared to 2001 is primarily attributed to reduced costs associated with conducting clinical trials and sponsored research for the TP10 programs, a decrease in manufacturing costs as a result of the timing of production runs for the travelers' vaccines programs, offset in part by an increase in manufacturing consultancy costs and facility-related expenses.

Selling, general and administrative expense increased $3,900, or 0.3%, to $1,325,600 for the third quarter of 2002 compared to $1,321,700 for the third quarter of 2001. The increase in expense in 2002 compared to 2001 is primarily due to increased corporate communications and legal costs, offset in part by a decrease in selling and marketing expense in 2002.

Amortization expense of goodwill decreased $145,200 for the third quarter of 2002 from the comparable period in 2001 as a result of the adoption of SFAS 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 $236,400, or 66.1%, to $121,300 for the third quarter of 2002 compared to $357,700 for the third quarter of 2001. The decrease is primarily due to



significantly lower interest rates and lower average cash balances during the third quarter of 2002 compared to the third quarter of 2001.

Nine-Month Period Ended September 30, 2002 as Compared with the Nine-Month Period Ended September 30, 2001

AVANT reported consolidated net loss of $10,354,100, or $.17 per share, for the nine months ended September 30, 2002, compared with a net loss of $15,987,600, or $.28 per share, for the nine months ended September 30, 2001. The weighted average common shares outstanding used to calculate net loss per common share was 60,460,300 in 2002 and 57,329,600 in 2001.

*Revenue:* Total revenue increased $3,483,800 to $5,894,000 for the first nine months of 2002 compared to $2,410,200 for the first nine months of 2001.

Product development and licensing revenue increased $3,468,500 to $5,601,600 for the first nine months of 2002 from $2,133,100 for the first nine months of 2001. In 2002, we recognized $1,900,000 receivable from Novartis in net termination fees, $3,154,700 in the amortization of nonrefundable license fees from Novartis and Pfizer, $375,000 in funded research from Pfizer, $62,500 in license fee and milestone payments from DynPort and $109,400 received in connection with government grants. The Novartis termination fee is non-recurring in nature and the Novartis deferred revenue of approximately $2,000,000 recognized due to the termination is also non-recurring revenue. In 2001, we recognized $1,154,700 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, $416,700 in funded research and development from Pfizer and $397,700 received in connection with government grants.

Product sales for the first nine months of 2002 totaled $292,400 compared to $277,100 for 2001 and were derived from sales of our Megan®Vac 1 salmonella vaccine product.

*Operating Expense:* Total operating expense decreased $3,107,200, or 15.7%, to $16,735,600 for the first nine months of 2002 compared to $19,842,800 for the first nine months of 2001. The decrease in total operating expense for the first nine months of 2002 compared to the first nine months of 2001 is primarily due to a reduction in costs associated with conducting sponsored research and clinical trials of TP10, offset in part by an increase in costs incurred in connection with AVANT's travelers' vaccine programs and CETi-1 clinical program.

Research and development expense decreased $3,236,200, or 21.4%, to $11,899,200 for the first nine months of 2002 compared to $15,135,400 for the first nine months of 2001. The decrease in 2002 compared to 2001 is primarily due to a reduction in clinical material costs and sponsored research and clinical trial costs associated with the TP10 programs, offset in part by increased consultancy costs and spending associated with the manufacture of clinical materials for the travelers' vaccines programs.

Selling, general and administrative expense increased $550,300, or 15.1%, to $4,199,000 for the first nine months of 2002 compared to $3,648,700 for the first nine months of 2001. The increase is primarily attributed to increased legal, consulting and insurance expenses, offset in part by a decrease in selling and marketing expense in 2002.

Amortization expense of goodwill decreased $435,600 in the first nine months of 2002 from the comparable period in 2001 as a result of the adoption of SFAS 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:* Net investment income decreased $1,047,500, or 68.2%, to $487,500 for the first nine months of 2002 compared to $1,535,000 for the first nine months of 2001. The decrease is primarily due to lower average cash balances and significantly lower interest rates during the first nine months of 2002 compared to the first nine months of 2001.



**LIQUIDITY AND CAPITAL RESOURCES**

AVANT ended the third quarter of 2002 with cash and cash equivalents of $26,314,000 compared to cash and cash equivalents of $42,665,900 at December 31, 2001.

Net cash used in operating activities increased to $15,732,300 for the first nine months of 2002 compared to $15,359,500 for the first nine months of 2001. The increase is attributed to increases in accounts receivable and decreases in accounts payable, accrued expenses and deferred revenue, offset by a decrease in net loss incurred in 2002 compared to 2001.

Net cash used in investing activities increased to $617,700 for the first nine months of 2002 compared to $586,100 for the first nine months of 2001. The increase is primarily due to the increased investment in patents and licenses, offset in part by decreased investment in property and equipment in 2002 compared to 2001.

Net cash used in financing activities was $1,900 for the first nine months of 2002 compared to net cash provided by financing activities of $505,500 for the first nine months of 2001. The decrease is due to a decrease in proceeds from the exercise of stock options and warrants, coupled with the purchases of treasury stock under a share repurchase plan.

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, 2003. 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. Through December 31, 2003, 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.

**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 September 30, 2002 and December 31, 2001 due to the short-term maturities of these instruments.

**Item 4. Controls and Procedures**

(a) Evaluation of disclosure controls and procedures.

As required by new Rule 13a-15 under the Securities Exchange Act of 1934, within the 90 days prior to the date of this report, the Company carried out an evaluation under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded



that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. In connection with the new rules, we currently are in the process of further reviewing and documenting our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal controls.

None.

**PART II — OTHER INFORMATION**

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

**(a) Exhibits**

None.

**(b) Reports on Form 8-K**

None.



**SIGNATURES**

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

**AVANT IMMUNOTHERAPEUTICS, INC.**

BY:

Dated: November 12, 2002

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

Dated: November 12, 2002

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



**Certification**

I, Una S. Ryan, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AVANT Immunotherapeutics, Inc.;

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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-14 and 15d-14) for the registrant and we have:

a. designed such disclosure controls and procedures 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 quarterly report is being prepared;

b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 12, 2002

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



**Certification**

I, Avery W. Catlin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AVANT Immunotherapeutics, Inc.;

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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-14 and 15d-14) for the registrant and we have:

a. designed such disclosure controls and procedures 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 quarterly report is being prepared;

b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 12, 2002

/s/ Avery W. Catlin
Avery W. Catlin
Senior Vice President and
Chief Financial Officer