UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2001

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.

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 November 5, 2001
Common Stock, $.001 par value	60,449,106

AVANT IMMUNOTHERAPEUTICS, INC.

FORM 10-Q

Quarter Ended September 30, 2001
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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

AVANT IMMUNOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEET
September 30, 2001 and December 31, 2000
(Unaudited)

	September 30, 2001	December 31, 2000
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 34,736,900	$ 50,177,000
Accounts Receivable	161,500	153,500
Inventories	78,900	59,200
Current Portion Lease Receivable	71,900	395,700
Prepaid Expenses and Other Current Assets	863,000	1,021,200
Total Current Assets	35,912,200	51,806,600
Property and Equipment, Net	1,084,000	1,037,900
Intangible and Other Assets	9,581,800	10,718,500
Total Assets	$ 46,578,000	$ 63,563,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 872,700	$ 902,300
Accrued Expenses	2,414,300	2,681,600
Current Portion Deferred Revenue	1,623,000	1,539,600
Current Portion Lease Payable	49,800	274,500
Total Current Liabilities	4,959,800	5,398,000
Long-Term Deferred Revenue	3,078,300	4,233,000
Stockholders' Equity:		
Common Stock, $.001 Par Value; 100,000,000 Shares Authorized; 57,390,600 Issued and Outstanding at September 30, 2001 and 57,144,200 Issued and Outstanding at December 31, 2000	57,400	57,100
Additional Paid-In Capital	209,700,500	209,195,300
Accumulated Deficit	(171,218,000)	(155,320,400)
Total Stockholders' Equity	38,539,900	53,932,000
Total Liabilities and Stockholders' Equity	$ 46,578,000	$ 63,563,000

See accompanying Notes to Consolidated Financial Statements (Unaudited)

AVANT IMMUNOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF OPERATIONS
For the Three Months Ended September 30, 2001 and 2000
(Unaudited)

	September 30, 2001	September 30, 2000
REVENUE:		
Product Development and Licensing Agreements	$ 663,800	$ 153,900
Product Sales	61,700	¾
Total Revenue	725,500	153,900
OPERATING EXPENSE:		
Research and Development	5,633,100	3,292,700
Selling, General and Administrative	1,321,700	1,050,500

Cost of Product Sales	8,400	¾
Amortization of Acquired Intangible Assets	344,000	137,300
Total Operating Expense	7,307,200	4,480,500
Operating Loss	(6,581,700)	(4,326,600)
Investment Income, Net	357,700	693,000
Net Loss	$ (6,224,000)	$ (3,633,600)
Basic and Diluted Net Loss Per Common Share	$ (0.11)	$ (0.07)
Weighted Average Common Shares Outstanding	57,379,700	54,143,700

See accompanying Notes to Consolidated Financial Statements (Unaudited)

AVANT IMMUNOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF OPERATIONS
For the Nine Months Ended September 30, 2001 and 2000
(Unaudited)

	September 30, 2001	September 30, 2000
REVENUE:		
Product Development and Licensing Agreements	$ 2,133,100	$ 461,600
Product Sales	277,100	¾
Total Revenue	2,410,200	461,600
OPERATING EXPENSE:		
Research and Development	15,135,400	7,072,700
Selling, General and Administrative	3,648,700	3,194,800
Cost of Product Sales	26,700	¾
Legal Settlements	¾	(500,000)
Amortization of Acquired Intangible Assets	1,032,000	411,900
Total Operating Expense	19,842,800	10,179,400
Operating Loss	(17,432,600)	(9,717,800)
Investment Income, Net	1,535,000	1,236,900
Net Loss	$ (15,897,600)	$ (8,480,900)
Basic and Diluted Net Loss Per Common Share	$ (0.28)	$ (0.17)
Weighted Average Common Shares Outstanding	57,329,600	51,347,300

See accompanying Notes to Consolidated Financial Statements (Unaudited)

AVANT IMMUNOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
For the Nine Months Ended September 30, 2001 and 2000
(Unaudited)

	September 30, 2001	September 30, 2000
Cash Flows from Operating Activities:		
Net Loss	$ (15,897,600)	$ (8,480,900)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	1,654,300	919,800
Write-off of Capitalized Patent Costs	22,400	¾
Changes in Assets and Liabilities:		
Accounts Receivable	(8,000)	¾
Inventories	(19,700)	¾
Prepaid Expenses and Other Current Assets	158,200	(190,700)
Accounts Payable and Accrued Expenses	(296,900)	276,200
Deferred Revenue	(1,071,300)	3,230,800
Lease Receivable	323,800	323,800
Lease Payable	(224,700)	(223,700)
Net Cash Used in Operating Activities	(15,359,500)	(4,144,700)
Cash Flows from Investing Activities:		
Acquisition of Property and Equipment	(456,300)	(125,300)

Decrease in Restricted Cash	¾	217,000
Increase in Patents and Licenses	(129,800)	(229,700)
Net Cash Used in Investing Activities	(586,100)	(138,000)
Cash Flows from Financing Activities:		
Proceeds from Exercise of Stock Options and Warrants	505,500	2,380,100
Net Proceeds from Stock Issuance	¾	36,788,600
Net Cash Provided by Financing Activities	505,500	39,168,700
Increase (Decrease) in Cash and Cash Equivalents	(15,440,100)	34,886,000
Cash and Cash Equivalents at Beginning of Period	50,177,000	13,619,000
Cash and Cash Equivalents at End of Period	$ 34,736,900	$ 48,505,000

See accompanying Notes to Consolidated Financial Statements (Unaudited)

AVANT IMMUNOTHERAPEUTICS, INC.
Notes to Consolidated Financial Statements (Unaudited)
September 30, 2001

(1) Nature of Business

AVANT Immunotherapeutics, Inc. ("AVANT") is a biopharmaceutical company engaged in the discovery, development and commercialization of products that harness the human immune response to prevent and treat disease. We are building our own business franchises in three areas. The first of these areas is in cardiac surgery where AVANT focuses on compounds with the potential to inhibit inappropriate activation of the complement cascade, a vital part of the body's immune defense system. Secondly, AVANT is developing a portfolio of oral vaccines aimed at protecting people traveling to areas where these diseases are endemic. Thirdly, AVANT is conducting clinical investigations with a proprietary therapeutic vaccine for the management of cholesterol. Additionally, through our corporate collaborations, we are developing a variety of infectious disease vaccines, including an oral human rotavirus vaccine.

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

(2) Interim Financial Statements

The accompanying unaudited consolidated financial statements for the nine months ended September 30, 2001 and 2000 include the consolidated accounts of AVANT, and have been prepared in accordance with generally accepted accounting principles and the instructions to Form 10-Q 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, 2001 and December 31, 2000, the results of operations for the quarters and nine months ended September 30, 2001 and 2000, and the cash flows for the nine months ended September 30, 2001 and 2000. The results of operations for the quarter and nine months ended September 30, 2001 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, 2000.

(3) New Accounting Pronouncements

In July 2001, the FASB issued SFAS No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill's impairment and that intangible assets other than goodwill be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001 and for all business combinations accounted for by the purchase method for which the date of acquisition is after June 30, 2001. The provisions of SFAS No. 142 will be effective for fiscal years beginning after December 15, 2001, and will thus be adopted by the Company, as required, in fiscal year 2002. The impact of SFAS No. 141 and SFAS No. 142 on the Company's financial statements has not yet been determined.

(4) Inventories

Inventories consist of finished products at September 30, 2001 and December 31, 2000.

(5) Property and Equipment

Property and equipment includes the following:

	September 30, 2001	December 31, 2000
Laboratory Equipment	$ 2,878,300	$ 2,800,500
Office Furniture and Equipment	1,482,100	1,355,600
Leasehold Improvements	1,214,200	962,200
Property and Equipment, Total	5,574,600	5,118,300
Less: Accumulated Depreciation and Amortization	(4,490,600)	(4,080,400)

	$ 1,084,000	$ 1,037,900

(6) Intangible and Other Assets

Intangible and other assets include the following:

	September 30, 2001	December 31, 2000
Capitalized Patent Costs	$ 2,430,300	$ 2,322,900
Less: Accumulated Amortization	(1,096,100)	(883,900)
Capitalized Patent Costs, Net	1,334,200	1,439,000
Acquired Intangible Assets:		
Goodwill	2,275,700	2,275,700
Collaborative Relationships	1,090,000	1,090,000
Assembled Workforce	625,400	625,400
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
	11,605,000	11,605,000
Less: Accumulated Amortization	(3,472,200)	(2,440,300)
Acquired Intangible Assets, Net	8,132,800	9,164,700
Other Non-Current Assets	114,800	114,800
	$ 9,581,800	$ 10,718,500

(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, 2001 and 2000 as its inclusion would have been anti-dilutive. A total of 4,819,600 and 4,860,200 stock options and warrants were excluded from the computation of weighted average common shares as of September 30, 2001 and 2000, respectively, as they were anti-dilutive.

(8) Acquisition of 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. The acquisition of Megan has been accounted for as a purchase. Consequently, the purchase price was allocated to the acquired assets and assumed liabilities based upon their fair value at the date of acquisition. The excess of the purchase price over the tangible assets acquired was assigned to acquired intangible assets, the components of which include core technology, developed technology, strategic partner agreement and assembled work force. These acquired intangible assets are being amortized on a straight-line basis over their estimated lives, which range from 5 to 17 years. An allocation of $9,012,300 was made to in-process research and development, which represented purchased in-process technology which had not yet reached technological feasibility and had no alternative future use. The amount was charged as an expense in our financial statements during the fourth quarter of 2000.

The following unaudited pro forma financial summary is presented as if the operations of AVANT and Megan were combined as of the beginning of the periods presented. The unaudited pro forma combined results are not necessarily indicative of the actual results that would have occurred had the acquisition been consummated at that date, or of the future operations of the combined entities. Nonrecurring charges, such as the acquired in-process research and development charge of $9,012,300, are not reflected in the following pro forma financial summary.

	For the Nine Months Ended September 30, 2000
Revenue	$ 1,266,900
Net loss	$ (10,426,900)
Basic and diluted net loss per share	$ (0.19)

(9) Subsequent Event

On October 17, 2001, AVANT completed a direct placement of approximately 3,057,900 shares of common stock to institutional investors. Net proceeds from the offering totaled approximately $13,575,200.

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

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 technologies with the ability to inhibit the complement system and 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, including Novartis Pharma AG, GlaxoSmithKline plc and Pfizer Inc.

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. We issued approximately 1,841,200 shares of AVANT's common stock in exchange for all of the outstanding capital stock of Megan, on the basis of 0.763542977 shares of AVANT common stock for each share of Megan preferred stock and 0.08115304 shares of AVANT common stock for each share of Megan common stock. We also assumed all of the outstanding options to purchase common stock of Megan under Megan's stock option plan. The purchase price of $17,332,000 consisted of (i) the issuance of 1,841,200 shares of AVANT common stock valued at $15,803,400, (ii) cash distributed to certain Megan shareholders in lieu of AVANT common stock totaling $236,700, (iii) the issuance of fully vested options to purchase AVANT common stock valued at $239,400 and (iv) severance and transaction costs totaling $1,052,500.

The acquisition of Megan has been accounted for as a purchase. Consequently, the purchase price was allocated to the acquired assets and assumed liabilities based upon their fair value at the date of acquisition. The excess of the purchase price over the tangible assets acquired was assigned to acquired intangible assets, the components of which include core technology, developed technology, strategic partner agreement and assembled work force. These acquired intangible assets are being amortized on a straight-line basis over their estimated lives which range from 5 to 17 years. An allocation of $9,012,300 was made to 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 amount was charged as an expense in our financial statements during the fourth quarter of 2000.

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 used for 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 September 30, 2001, 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 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, we 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. AVANT issued 14,036,400 shares and warrants to purchase 1,811,200 shares of its common stock in exchange for all of the outstanding common stock of VRI. The acquisition has been accounted for as a purchase. Consequently, the purchase price was allocated to the acquired assets and assumed liabilities based upon their fair value at the date of acquisition. The excess of the purchase price over the tangible assets acquired was assigned to collaborative relationships, work force and goodwill and is being amortized on a straight line basis over 12 to 60 months. An allocation of $44,630,000 was made to IPR&D which represented purchased in-process technology which had not yet reached technological feasibility and had no alternative future use. The amount was charged as an expense in our financial statements during the third quarter of 1998.

NEW DEVELOPMENTS

Complement Inhibitors: In 1997, we entered into an agreement with Novartis Pharma AG ("Novartis") relating to the development of TP10 for use in transplantation. We granted Novartis a two-year option to license TP10 with exclusive worldwide marketing rights (except Japan) in the field of transplantation. In July 1999, Novartis exercised its option to license TP10. In December 1999, the Novartis agreement was amended to include marketing rights for Japan. 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 have elected to independently develop TP10 for cardiac surgery. In September 1999, we initiated an open-label, Phase I/II trial of TP10 in infants undergoing cardiac surgery for congenital heart defects. The trial evaluated the ability of TP10 to mitigate the injury to the heart and other organs that occurs when patients are placed on cardiopulmonary bypass circuits. TP10 was well tolerated in the study population and results of this Phase I/II trial were presented at the Society of Cardiovascular Anesthesiologists Annual Meeting in May 2000 and at the American Heart Association's Annual Meeting in November 2000. In March 2000, we received orphan drug designation for TP10 in infants undergoing cardiac surgery.

AVANT is conducting two Phase IIb studies of TP10 in pediatric cardiac surgery utilizing cardiopulmonary bypass. The first study, begun earlier this year, is in babies born with hypoplastic left heart syndrome who often have high morbidity and mortality after heart surgery. The second study in the pediatric cardiac surgery setting investigates the use of TP10 in a lower risk infant population. The objective of these studies is to assess the ability of TP10 to mitigate the injury to the heart, brain and other organs that occurs when patients are placed on cardiopulmonary bypass circuits, thus potentially improving post-operative outcomes.

On September 27, 2001, AVANT announced the FDA had removed a clinical hold on the enrollment of new patients in AVANT's two Phase IIb studies of TP10 in infants undergoing cardiac surgery and said the company expected to resume enrollment as soon as possible. AVANT had initially announced its suspension of enrollment in the clinical studies on August 1, 2001, following receipt from the Data Safety Monitoring Board (DSMB) of a request for additional detailed information from these studies, including patient records for reported serious adverse events. While the DSMB met, reviewed the information requested and unanimously recommended patient enrollment be resumed with the addition of new laboratory tests in the study protocol, the FDA placed the pediatric programs on clinical hold pending their review of the same data.

AVANT has recently completed enrollment in a placebo-controlled Phase II trial in approximately 600 adult patients undergoing cardiac surgery utilizing cardiopulmonary bypass. This 30-center study is a dose-ranging study that will allow us to further define our clinical endpoints in the adult patient population before moving ahead to a number of pivotal clinical trials. AVANT expects to release preliminary data from the adult trial around year-end 2001. The objective of this study, as well as the two infant cardiac by-pass trials, is to assess the ability of TP10 to mitigate the injury to the heart, brain and other organs that occurs when patients are placed on cardiopulmonary bypass circuits, thus potentially improving post-operative outcomes. AVANT may partner the cardiac surgery program when additional clinical data become available.

Cholesterol Treatment Vaccine: We are developing a therapeutic 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 and LDL. We are developing a 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 in rabbits, which have demonstrated the ability of the CETi-1 vaccine to elevate HDL and reduce the development of blood vessel lesions.

In 1999, we initiated a double-blind placebo controlled, Phase I clinical trial of our CETi-1 vaccine in adult volunteers. The object of the study was to demonstrate the safety of single administrations of the vaccine at four different dosage strengths. 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.

In February 2001, AVANT announced preliminary results from a double-blinded placebo controlled extension of the earlier completed Phase I trial of our CETi-1 vaccine in healthy adult volunteers. Results from the extension study showed measurable antibody titers in all dose groups treated with study medication, suggesting a dose-response relationship. In August 2001, AVANT initiated a placebo-controlled Phase II study of its CETi-1 vaccine 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. The study is being conducted at the Chicago Center for Clinical Research and Rush-Presbyterian-St. Luke's Medical Center. As clinical data become available, we plan to seek a corporate partner to complete development and to commercialize the CETi-1 vaccine.

Cholera Vaccine: We are developing a single dose, oral cholera vaccine using a live, genetically attenuated cholera strain. Based on this technology, discovered in academia, we have developed the vaccine through early Phase II trials. We then negotiated a collaboration agreement under which a Phase IIb trial was performed and funded by the Walter Reed Army Institute of Research (WRAIR) and the National Institutes of Health (NIH). This trial, initiated in October 2000, was designed to test the safety, immunogenicity and protective capacity of AVANT's single dose, oral cholera vaccine, Peru-15, against a challenge with live virulent cholera. In May 2001, we announced results from this Phase IIb human challenge study. Peru-15 showed 100% protection against moderate and severe diarrhea and 93% protection against any diarrhea. The study results suggest that, if confirmed by further investigation, Peru-15 may be an excellent candidate as a potential single dose, oral vaccine for travelers going to areas where cholera is endemic.

AVANT has entered into a manufacturing agreement with Bio Sidus S.A. of Buenos Aires, Argentina for the production of commercial quantities of Peru-15. AVANT is moving rapidly to complete the manufacture of cGMP grade material and plans to initiate pivotal trials in the first half of 2002. Development of a safe, effective cholera vaccine is the first step in establishing AVANT's travelers' vaccine franchise. AVANT has also conducted initial clinical studies of our single dose, oral typhoid vaccine and has a shigella vaccine in pre-clinical development. With the acquisition of Megan Health, Inc., AVANT has gained access to technologies for developing vaccines against *Campylobacter* and *E. coli*, two additional causes of serious diarrheal diseases worldwide.

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 GlaxoSmithKline plc ("Glaxo"). In 2000, 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. During the next twelve months, AVANT expects Glaxo to initiate Phase III studies of its investigational rotavirus vaccine, Rotarix™. The design, timing and execution of the clinical program for Rotarix™ is the responsibility of GlaxoSmithKline. Assuming product development and commercialization continues satisfactorily, we expect that Glaxo will pay us additional milestones and a royalty based on sales.

TECHNOLOGY LICENSING

AVANT has adopted a business strategy of out-licensing technology that does not match the Company's development focus or where the company lacks sufficient resources for the technology's efficient development. For example, when AVANT acquired Megan Health, 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: On October 10, 2001, AVANT announced the granting of a license to DynPort Vaccine Company LLC ("DVC") for exclusive rights to use certain components of AVANT's vaccine technology. Financial terms of the agreement with DVC include license fees, milestone payments and royalties. DVC, a private company, is chartered with providing an integrated approach for the advanced development of specific vaccines and other products to protect against the threat of biological warfare agents. 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 leverage our vaccine technology in an area that AVANT does not plan to pursue itself.

Formation of Parallel Solutions: During October 2001, AVANT spun out its polyphosphazene polymer adjuvant business (the "PCPP business"), including Adjumer® and Micromer®, into a newly formed, privately held company, Parallel Solutions, Inc. ("Parallel"), while retaining 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 Pasteur license agreements to Parallel. The technology had no book value and therefore, our investment in Parallel is being carried at no value and will be accounted for on the cost method.

RESULTS OF OPERATIONS

Three Month Period Ended September 30, 2001 as Compared
With the Three Month Period Ended September 30, 2000

AVANT reported consolidated net loss of $6,224,000, or $.11 per share, for the quarter ended September 30, 2001, compared with a net loss of $3,633,600, or $.07 per share, for the quarter ended September 30, 2000. The weighted average common shares outstanding used to calculate net loss per common share was 57,379,700 in 2001 and 54,143,700 in 2000.

Revenue: Total revenue increased $571,600 to $725,500 for the third quarter of 2001 compared to $153,900 for the third quarter of 2000.

Product development and licensing revenue increased $509,900 to $663,800 for the third quarter of 2001 from $153,900 for the third quarter of 2000. 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. In 2000, product development and licensing revenue consisted primarily of the amortization of a nonrefundable license fee associated with our agreement with Novartis.

Product sales for the third quarter of 2001 totaled $61,700 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. There were no product sales recorded in 2000.

Operating Expense: Total operating expense increased $2,826,700, or 63.1%, to $7,307,200 for the third quarter of 2001 compared to $4,480,500 for the third quarter of 2000. The increase in total operating expense for 2001 compared to 2000 is primarily due to increased clinical trials costs and clinical materials costs incurred in connection with AVANT's travelers' vaccines, TP10 and CETi-1 clinical programs, as well as the addition of the operating costs of Megan Health, which AVANT acquired in December 2000.

Research and development expense increased $2,340,400, or 71.1%, to $5,633,100 for the third quarter of 2001 from $3,292,700 for the third quarter of 2000. The increase in 2001 compared to 2000 is primarily due to costs associated with conducting clinical trials of CETi-1 and TP10, an increase in expense associated with the manufacture of clinical materials for these programs and the travelers' vaccines program, an increase in research and development headcount and the addition of Megan's research and development expense in 2001.

Selling, general and administrative expense increased $271,200, or 25.8%, to $1,321,700 for the third quarter of 2001 compared to $1,050,500 for the third quarter of 2000. The increase in expense in 2001 compared to 2000 is primarily attributed to an increase in legal expenses and consulting costs as well as the addition of Megan's selling, general and administrative expense in 2001.

Amortization expense of acquired intangible assets increased $206,700 to $344,000 for the third quarter of 2001 from $137,300 in the comparable 2000 quarter as a result of the acquisition of Megan.

Investment Income, Net: Net investment income decreased $335,300, or 48.4%, to $357,700 for the third quarter of 2001 compared to $693,000 for the third quarter of 2000. The decrease is primarily due to lower average cash balances and lower interest rates during the third quarter of 2001 compared to the third quarter of 2000.

Nine-Month Period Ended September 30, 2001 as Compared
with the Nine Month Period Ended September 30, 2000

AVANT reported consolidated net loss of $15,897,600, or $.28 per share, for the nine months ended September 30, 2001, compared with a net loss of $8,480,900, or $.17 per share, for the nine months ended September 30, 2000. The weighted average common shares outstanding used to calculate net loss per common share was 57,329,600 in 2001 and 51,347,300 in 2000.

Revenue: Total revenue increased $1,948,600 to $2,410,200 for the first nine months of 2001 compared to $461,600 for the first nine months of 2000.

Product development and licensing revenue increased $1,671,500 to $2,133,100 for the first nine months of 2001 from $461,600 for the first nine months of 2000. In 2001, we recognized $1,154,700 in the amortization of nonrefundable license fees from Novartis and Pfizer, $164,000 from Innogenetics, Inc. as a one-time royalty fee paid 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. In 2000, product development and licensing revenue consisted primarily of the amortization of a nonrefundable license fee associated with our agreement with Novartis.

Product sales for the first nine months of 2001 totaled $277,100 and were derived from sales of our Megan®Vac 1 salmonella vaccine product. There were no product sales recorded in 2000.

Operating Expense: Total operating expense increased $9,663,400, or 94.9%, to $19,842,800 for the first nine months of 2001 compared to $10,179,400 for the first nine months of 2000. The increase in total operating expense for the first nine months of 2001 compared to the first nine months of 2000 is primarily due to increased clinical trials costs and clinical materials costs incurred in connection with AVANT's travelers' vaccines, TP10 and CETi-1 clinical programs, as well as the addition of the operating costs of Megan Health. During the first quarter of 2000, we received legal settlement payments totaling $500,000 from the resolution of disputes arising from contractual arrangements which were recorded as a credit to expense.

Research and development expense increased $8,062,700, or 114.0%, to $15,135,400 for the first nine months of 2001 compared to $7,072,700 for the first nine months of 2000. The increase in 2001 compared to 2000 is primarily due to costs associated with conducting clinical trials of CETi-1 and TP10, an increase in expense associated with the manufacture of clinical materials for these programs and the travelers' vaccines program, an increase in research and development headcount and the addition of Megan's research and development expense in 2001.

Selling, general and administrative expense increased $453,900, or 14.2%, to $3,648,700 for the first nine months of 2001 compared to $3,194,800 for the first nine months of 2000. The increase is primarily attributed to the addition of Megan's selling, general and administrative expenses in 2001 and increased legal expenses and consulting costs.

Amortization expense of acquired intangible assets increased $620,100 to $1,032,000 in the first nine months of 2001 from $411,900 in the comparable 2000 period as a result of the acquisition of Megan.

Investment Income, Net: Net investment income increased $298,100, or 24.1%, to $1,535,000 for the first nine months of 2001 compared to $1,236,900 for the first nine months of 2000. The increase is primarily due to higher average cash balances offset by lower interest rates during the first nine months of 2001 compared to the first nine months of 2000.

LIQUIDITY AND CAPITAL RESOURCES

AVANT ended the third quarter of 2001 with cash and cash equivalents of $34,736,900 compared to cash and cash equivalents of $50,177,000 at December 31, 2000.

Net cash used in operating activities increased significantly to $15,359,500 for the first nine months of 2001 compared to $4,144,700 for the first nine months of 2000. The increase is primarily attributed to the increase in net loss incurred in 2001 compared to 2000 and the recording of deferred revenue in 2000 as a result of Novartis exercising its option to license TP10 for transplantation.

Net cash used in investing activities increased to $586,100 for the first nine months of 2001 compared to $138,000 for the first nine months of 2000. The increase is primarily due to increased investment in property and equipment in 2001 compared to 2000 and the reduction in restricted cash recorded in 2000.

Net cash provided by financing activities decreased to $505,500 for the first nine months of 2001 compared to $39,168,700 for the first nine months of 2000. The decrease is primarily due to a decrease in proceeds from the exercise of stock options and warrants and the recording of net proceeds of $34,470,900 and $2,307,700 in 2000 from stock issued in a private placement and stock issued to Novartis, respectively.

On October 17, 2001, AVANT completed a direct placement of approximately 3,057,900 shares of common stock to institutional investors. Net proceeds from the offering totaled approximately $13,575,200.

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, 2001. 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 2001, 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.

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, 2001 and December 31, 2000 due to the short-term maturities of these instruments.

PART II — OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

(b) Reports on Form 8-K

We filed a Current Report on Form 8-K on December 12, 2000 reporting our acquisition of Megan Health, Inc., pursuant to an Agreement and Plan of Merger dated as of November 20, 2000 by and among AVANT, AVANT Acquisition Corp. and Megan Health, Inc. Under the terms of the Agreement, Megan Health, Inc. became a wholly owned subsidiary of AVANT. We amended the Current Report on Form 8-K on January 30, 2001 and July 3, 2001 and the amendments include proforma financial statements.

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 6, 2001

/s/ Una S. Ryan

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

Dated: November 6, 2001

/s/ Avery W. Catlin

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