
UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): October 21, 2004

Commission file number 0-15006

AVANT Immunotherapeutics, Inc. (Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

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

119 Fourth Avenue Needham, Massachusetts 02494 (Address of principal executive offices, including zip code)

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

(Former name, if changed since last report) -----

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- [] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- [] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On Ocotber 21, 2004, AVANT Immunotherapeutics, Inc. issued a press release announcing its financial results for the third quarter of 2004. The full text of the press release is furnished as Exhibit 99.1 hereto is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

Press Release of AVANT Immunotherapeutics, Inc. dated October 21, 99.1

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SIGNATURE

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

AVANT Immunotherapeutics, Inc.

By: /s/ Avery W. Catlin Dated: October 21, 2004

Avery W. Catlin

Senior Vice President and

Chief Financial Officer

Exhibit Index

99.1 Press Release of AVANT Immunotherapeutics, Inc. dated October 21, 2004.

NEEDHAM, Mass.--(BUSINESS WIRE)--Oct. 21, 2004--AVANT Immunotherapeutics, Inc. (Nasdaq: AVAN) today reported a net loss of \$3.7 million, or \$.05 per share, for the third quarter of 2004 compared with \$2.1 million, or \$.03 per share, for the third quarter of 2003. For the nine months ended September 30, 2004, the net loss was \$9.5 million, or \$.13 per share, compared with \$8.7 million, or \$.14 per share, for the first nine months of 2003. The increase in net loss between periods primarily reflects increased research and development expenses due to an increase in clinical trial costs associated with AVANT's ongoing TP10 Phase IIb study in women undergoing cardiac bypass surgery and TP10 contract manufacturing costs incurred for process development and scale-up work in preparation for the production of Phase III clinical materials in 2005. At September 30, 2004, AVANT reported cash and cash equivalents of \$35.2 million.

Revenues for the third guarter of 2004 were \$527,600 compared with revenues of \$2 million for the third quarter of the prior year. The decrease reflects a reduction in government contract revenue in 2004 compared to 2003 and the recognition of a \$1 million milestone payment from GlaxoSmithKline in the third quarter of 2003 upon initiation of Phase III trials of the Rotarix(R) rotavirus vaccine. Revenues were \$4.5 million for the nine months ended September 30, 2004, compared with revenues of \$3.8 million for the first nine months of 2003. The increase in revenues results primarily from the recognition of \$1 million in revenue from DynPort Vaccine Company LLC ("DVC") for rPA clinical materials and an upfront license fee of \$1 million from AdProTech, Ltd. in the first quarter of 2004, offset by the recognition of a GlaxoSmithKline milestone received in 2003. Operating expense increased \$1,603,100 in the first nine months of 2004 compared to 2003, primarily as a result of clinical trials costs and contract manufacturing costs incurred on the company's TP10 complement inhibitor program. We had higher investment income in 2004 reflecting higher average cash balances between periods.

Una S. Ryan, Ph.D., AVANT's President and Chief Executive Officer, said, "These financial results were consistent with our expectations and we remain on track to meet our forecasts for the full year. We are also pleased with the progress of our product development programs during the first nine months of 2004."

During the third quarter, AVANT had several noteworthy accomplishments which further prepare us to become a commercial company including:

- -- We were delighted to announce that our partner GlaxoSmithKline (GSK) had received marketing approval from the Mexican Board of Health for Rotarix(R), our two-dose oral vaccine against rotavirus. This is the first commercial approval for this important healthcare product, and we expect to hear from Glaxo regarding additional approvals over the coming year.
- -- The Defense Appropriations Bill for Fiscal Year 2005, passed by Congress in July, commits \$2.8 million to the continued development of our oral combination vaccine against anthrax and plaque.
- -- Construction is nearing completion at our pilot manufacturing facility in Fall River. The Opening Ceremony with Massachusetts Governor Romney speaking is scheduled for November 5th. The facility will produce our anthrax-plague vaccine and implement our VitriLife(R) technology, offering AVANT new opportunities for corporate partnering.

Rotarix(R) Vaccine

The July approval for Rotarix(R) in Mexico is just a first step. GSK expects to achieve a series of rolling launches throughout Latin America and Southeast Asia - two areas of greatest need - over the coming year, followed by Europe and other markets. According to published reports, marketing applications are pending in 12 additional Latin American countries.

Rotarix is an extremely important product from a global health needs perspective. Rotavirus infection is the leading cause of severe diarrhea and vomiting in infants and young children and globally is responsible for about 440,000 deaths per year - nearly a child a minute. The majority of these deaths occur in the Indian subcontinent, sub-Saharan Africa and South America. GSK has stated that the potential annual market for a successful rotavirus vaccine approximates \$1.8 billion dollars - with about half that market potential outside the United States.

GSK has not yet unveiled U.S. launch plans for Rotarix(R). We

would expect that based on the extensive clinical data that GSK is accruing worldwide on Rotarix(R), they will ultimately seek to enter the U.S. market with a vaccine which we believe would be highly competitive and whose safety and efficacy is well proven through studies in more than 70,000 infants.

TP10 for Cardiac Surgery

Enrollment of the Phase IIb study in women undergoing cardiac bypass surgery at approximately 30 clinical sites has progressed slower than we anticipated. We now expect to complete enrollment as soon as possible and report out results in the first half of 2005. We are working closely with our manufacturing partner, Lonza Biologics plc, to complete process development and scale-up efforts in preparation for the production of Phase III clinical materials and the start of that registration-directed trial by year-end 2005.

In September, Circulation published results of the TP10 double-blind, placebo-controlled Phase II study in 564 adult patients undergoing cardiac surgery on cardiopulmonary bypass (CPB), which as previously disclosed, showed that TP10 significantly decreased the incidence of mortality and acute myocardial infarction (heart attack) in male patients. Also as previously reported, the study did not show a similar benefit in female patients. Since treatment for both genders is desirable, the goals of the ongoing Phase IIb female study are to clarify the effect that TP10 hs in women undergoing cardiac surgery, as well as augment the safety data for the female patient population.

CETP Vaccine for Cholesterol Management

We continue to evaluate a number of new adjuvants and delivery technologies for our CETP vaccine in animal models and expect to choose the approach eliciting the most robust antibody response by year-end. We are strongly committed to this program and it is our plan to have a CETP vaccine back into the clinic towards the end of 2005.

Webcast and Conference Call

Dr. Ryan and Mr. Catlin will host a conference call at 11:00 AM EDT on Thursday, October 21, 2004 to discuss AVANT's Third Quarter 2004 financial results. To access the conference call, dial 800-329-9097 (within the United States), or 617-614-4929 (if calling from outside the U.S.). The passcode for participants is 63247445. An audio replay will be available approximately two hours after the call for approximately one week and can be accessed by dialing 888-286-8010 (within the U.S.), or 617-801-6888 (if calling from outside the U.S.). The passcode I.D.# is 60250729.

A live webcast of the conference call, together with this press release, can be accessed through the company's web site www.avantimmune.com in the Investor Information section. In order to access the webcast, your PC must have a sound card, speakers and Windows Media Player software. It is recommended that you configure your PC in advance of the webcast as the software download and installation can take several minutes. In addition, the call and webcast will be archived and can be accessed through the same link. Additionally, a copy of this press release is available by contacting Investor Relations at (781) 433-0771.

AVANT Immunotherapeutics, Inc. discovers, develops and sells innovative vaccines and therapeutics that harness the human immune system to prevent and treat disease. The company has developed a broad, well-staged pipeline of vaccines and therapeutics for large, high-value, under-served markets. These include an oral human rotavirus vaccine, which gained its first marketing approval in Mexico in July 2004. Six of AVANT's products are in clinical development, including a treatment to reduce complement-mediated tissue damage associated with cardiac by-pass surgery, and a novel vaccine for cholesterol management. AVANT has also assembled a technology platform that enables the creation of rapid-protecting, single-dose, oral vaccines that remain stable without refrigeration. The company is developing applications of this vaccine technology in four areas: biodefense, travelers' vaccines, global health needs, and human food safety. AVANT's goal is to demonstrate proof-of-concept for its products before leveraging further development through both traditional pharmaceutical partnerships and collaborations with governmental and other organizations.

Additional information on AVANT Immunotherapeutics, Inc. can be obtained through our site on the World Wide Web: http://www.avantimmune.com.

Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995: This release includes forward-looking statements

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. Investors 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 integration of multiple technologies and programs; (2) the ability to adapt AVANT's vectoring systems to develop new, safe and effective orally administered vaccines against anthrax and plague or other bioterrorism threats or emerging health care threats; (3) the ability to successfully complete development and commercialization of TP10, CETi-1, CholeraGarde(R) (Peru-15), Ty800 and other products; (4) the cost, timing, scope and results of ongoing safety and efficacy trials of TP10, CETi-1, CholeraGarde(R) (Peru-15), Ty800 and other preclinical and clinical testing; (5) the ability to successfully complete product research and further development, including animal, pre-clinical and clinical studies of TP10, CETi-1, CholeraGarde(R) (Peru-15), Ty800 and other products; (6) the ability of the Company to manage multiple late stage clinical trials for a variety of product candidates; (7) royalty revenues from product sales of Rotarix(R), Megan(R)Vac 1, Megan(R)Egg and other future products; (8) changes in existing and potential relationships with corporate collaborators; (9) the availability, cost, delivery and quality of clinical and commercial grade materials supplied by contract manufacturers; (10) the timing, cost and uncertainty of obtaining regulatory approvals to use TP10, CETi-1, CholeraGarde(R) (Peru-15) and Ty800, among other purposes, for adults undergoing cardiac surgery, to raise serum HDL cholesterol levels and to protect travelers and people in endemic regions from diarrhea causing diseases, respectively; (11) the ability to obtain substantial additional funding; (12) the ability to develop and commercialize products before competitors; (13) the ability to retain certain members of management; and (14) other factors detailed from time to time in filings with the Securities and Exchange Commission. We expressly disclaim any responsibility to update forward-looking statements.

which reflect AVANT's current views with respect to future events and financial performance. These forward-looking statements are based on

AVANT IMMUNOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS DATA

	Quarter Ended September 30,		Year to Date Ended September 30,		
REVENUE	2004 (Unaud	2004 2003 (Unaudited)		2004 2003 (Unaudited)	
-					
Product Development and Licensing Agreements Government	\$144,300	\$1,232,900	\$2,393,100	\$1,620,000	
Contract Revenue Product Royalties	334,200 49,100	733,700 48,500	1,928,800 129,400	2,029,300 125,900	
Total Revenue	527,600	2,015,100	4,451,300	3,775,200	
OPERATING EXPENSE					
Research and Development General and	2,805,800	2,510,100	9,626,800	7,876,000	
Administrative Amortization of Acquired	1,290,600	1,423,700	3,852,400	4,000,100	
Intangible Assets	248,800	248,800	746,400	746,400	
Total Operating Expense	4,345,200	4,182,600	14,225,600	12,622,500	
Operating Loss	(3,817,600)	(2,167,500)	(9,774,300)	(8,847,300)	
Investment and					

Other Income, Net	120,400	51,800	268,900	186,100
Net Loss	\$(3,697,200)	\$(2,115,700)	\$(9,505,400)	\$(8,661,200)
Basic and Diluted Net Loss per Common Share	\$(0.05)	\$(0.03)	\$(0.13)	\$(0.14)
Weighted Average Common Shares Outstanding	74,118,300	64,703,000	72,510,600	61,773,500
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CONDENSED CONSOLIDATED BALANCE SHEETS

Sept. 30,

Dec.31,

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ASSETS	2004 (Unaudited)	2003			
Cash and Cash Equivalents Other Current Assets Property and Equipment, net Intangible and Other Assets, net	, ,	\$20,251,000 2,058,000 912,700 8,083,400			
Total Assets		\$31,305,100			
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current Liabilities Noncurrent Liabilities Stockholders' Equity	\$3,812,100 342,700 41,979,000	\$3,385,400 - 27,919,700			
Total Liabilities and Stockholders' Equity	\$46,133,800	\$31,305,100			

CONTACT: AVANT Immunotherapeutics, Inc.

President and CEO

Una S. Ryan, Ph.D., 781-433-0771

Chief Financial Officer

Avery W. Catlin, 781-433-0771

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or

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