
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): March 2, 2005

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 March 2, 2005, AVANT Immunotherapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and full year 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.

99.1 Press Release of AVANT Immunotherapeutics, Inc. dated March 2, 2005.

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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.

Dated: March 2, 2005 /s/ Avery W. Catlin By:

Avery W. Catlin Senior Vice President and Chief Financial Officer

Exhibit Index

99.1 Press Release of AVANT Immunotherapeutics, Inc. dated March 2, 2005.

AVANT Reports Fourth Quarter and Fiscal 2004 Financial Results - Provides 2005 Financial Guidance -

NEEDHAM, Mass.--(BUSINESS WIRE)--March 2, 2005--AVANT Immunotherapeutics, Inc. (Nasdaq: AVAN) today reported financial results for the fourth quarter and year ended December 31, 2004. The Company reported a net loss of \$3.7 million, or \$0.05 per share, for the fourth quarter of 2004 compared to a net loss of \$2.9 million, or \$0.05 per share, for the fourth quarter of 2003. For the twelve months ended December 31, 2004, the net loss was \$13.2 million, or \$.18 per share, compared with \$12.7 million, or \$.20 per share, for the twelve 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. The increase in operating expense was partially offset by an increase in product development and license agreements revenue. At December 31, 2004, the Company reported cash and cash equivalents of \$31.7 million.

Revenues for the fourth quarter of 2004 were \$2,407,300 compared with revenues of \$857,700 for the fourth quarter of 2003. The increase reflects the recognition of a milestone fee of \$2 million from GlaxoSmithKline (GSK) for the European filing of an application for market approval of the Rotarix(R) rotavirus vaccine. This milestone revenue was offset by a reduction in government contract revenue during the quarter in 2004 compared to 2003. For the year ended December 31, 2004, revenues were \$6.9 million compared with revenues of \$4.6 million for 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, an upfront license fee of \$1 million from AdProTech, Ltd. and the previously mentioned \$2 million milestone fee from GSK, offset by a reduction in government contract revenue. Operating expense increased \$4,074,000 in 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. In the fourth quarter of 2004, AVANT recorded \$300,000 in cost of revenue associated with the milestone fee from GSK. Investment income increased in 2004, reflecting higher average cash balances and interest rates between periods. In 2003, AVANT changed its accounting for patent costs and now expenses patent costs as incurred. As a result of this change, the company recorded a non-cash charge for the cumulative effect of the change in accounting principle of \$1.2 million, or \$.02 loss per share for the year ended December 31, 2003.

"For AVANT, 2004 was a year of significant milestones, capped by the first commercial approval of a human healthcare product from our extensive portfolio of next-generation vaccines," said Una S. Ryan, Ph.D., President and Chief Executive Officer of AVANT Immunotherapeutics, Inc. "That product, our Rotarix(R) rotavirus vaccine, was approved in Mexico in July and has now been launched by our partner GSK. This and other significant events that occurred during the year have brought AVANT closer to becoming a commercial company and to realizing the value of our technologies and products."

Other key events of 2004 included:

- -- The initiation of a Phase IIb study of TP10, our novel inhibitor of complement-mediated inflammation, in approximately 300 women undergoing open-heart surgery.
- -- The completion of a financing of approximately \$25 million, which at the time provided cash balances to cover our anticipated requirements for approximately two years.
- -- The opening of our state-of-the-art vaccine manufacturing facility in Fall River, Massachusetts with funding from MassDevelopment.
- -- Completion of enrollment of toddlers and infants in a Phase II clinical trial in Bangladesh of AVANT's cholera vaccine, CholeraGarde(R) by our partner, the International Vaccine Institute. AVANT announced positive preliminary results of the adult portion of this clinical trial in early 2004.
- -- Receipt of \$2.8 million in the 2005 Defense Appropriations Bill to support preclinical development of our oral combination anthrax/plague vaccine program.

- -- We announced that GSK had filed in late 2004 for market approval of Rotarix(R) with the European regulatory authorities, triggering a \$2 million milestone payment to AVANT.
- -- Also in January, GSK announced the launch of Rotarix(R) in Mexico, representing the first step in a series of global product launches to begin this year.

Dr. Ryan continued, "We were very pleased that our partner GSK gained approval for Rotarix(R) in Mexico during 2004, which represents just the first in an expected series of worldwide approvals for that product. GSK plans to launch in additional Latin American countries as well as Asia Pacific countries during the course of 2005. Addressing a worldwide market opportunity estimated by GSK at \$1.8 billion, they have already filed for market approval in more than 20 countries worldwide as well as with the European regulatory authorities. Royalty revenues to AVANT from Rotarix(R) sales should begin in the first half of 2005, with estimates totaling about \$1 to \$2 million for the year and increasing over the next several years as more countries approve this much needed product."

Dr. Ryan continued, "The opening of our new vaccine manufacturing facility in Fall River, Massachusetts also represents a key event for AVANT. This facility will produce AVANT's oral combination vaccine against biodefense, as well as our travelers' vaccines for clinical trials and eventual commercial sale. Importantly, this facility will also implement our VitriLife(R) preservation technology, the means to producing vaccines and therapeutic proteins that are room temperature stable without the need for refrigeration. This manufacturing capability, while important for AVANT's own products, may also provide revenue-generating opportunities to apply this technology to the products of others."

Clinical Development Programs

AVANT has a variety of programs in clinical development, many of which are supported by major companies, governmental agencies or international health organizations. Major programs, in addition to the Rotarix(R) vaccine discussed above, include TP-10, the company's complement inhibitor; CETi, a vaccine approach to cholesterol management; oral vaccines against cholera, typhoid fever and other important diarrheal diseases; and oral vaccines for biodefense. AVANT has assembled a broad portfolio of technologies and intellectual property that give it a strong competitive position in vaccines and immunotherapeutics.

TP-10: In the third quarter of 2005, AVANT expects to announce results from a blinded, placebo-controlled Phase IIb study of TP10, its complement inhibitor, in up to 300 females undergoing cardiac by-pass surgery. The aim of the trial is to augment the safety data for TP10 and further define its effect in women before advancing to a Phase III study. In addition, AVANT is continuing process development and scale-up efforts with a contract manufacturer in preparation for the production of Phase III clinical materials. AVANT is seeking to partner the TP10 program prior to starting a Phase III trial.

CETi: Phase II clinical results showed that our CETi vaccine can raise heart-protective HDL cholesterol levels by eliciting antibodies that block the transfer of cholesterol from HDL to LDL. Low levels of HDL are a key risk factor for atherosclerosis, a leading cause of deaths due to heart attacks and strokes. In preclinical testing, we have identified a new adjuvanted formulation for the vaccine that elicits more than a 10-fold increase in anti-CETP antibody titers when compared to the current CETi-1 vaccine. We have contracted for the production of GMP peptide for the newly formulated vaccine and we expect to complete toxicology, release and stability studies in 2005 consistent with the goal of having CETi back into the clinic within approximately twelve months.

Next-Generation Oral Vaccines: AVANT is developing "next generation" vaccines for a variety of needs including biodefense, global health, travelers' and food safety. Each of these vaccines is designed to provide rapid protection with a single, oral dose. Additionally, we expect the use of AVANT's proprietary VitriLife(R) preservation technology to give these vaccines room temperature stability, enabling them to be shipped and stored without refrigeration. This feature makes AVANT's vaccines uniquely suited to address both large commercial markets and serious world health needs. VitriLife(R) technology also reduces the time and cost of vaccine manufacture, further adding to the competitiveness of AVANT's vaccines.

In mid-2005, AVANT expects its partner, the International Vaccine Institute (IVI), to announce results of the pediatric portion of the

Phase II trial of AVANT's oral cholera vaccine. This trial has been ongoing in Bangladesh where cholera is endemic. Previously announced results in the adult portion of the trial showed the vaccine to be well tolerated and highly immunogenic against the cholera organism. AVANT is now seeking third party funding to pay for Phase III clinical field studies of this product. In addition, the National Institutes of Health (NIH) has funded the manufacture of AVANT's typhoid fever vaccine, Ty800, for clinical testing and expects to initiate a Phase I/II clinical trial in the first half of 2005 aimed at demonstrating the safety and immunogenicity of the Ty800 vaccine. AVANT is also developing three additional bacterial vaccines against enterotoxigenic E. coli, Shigella and Campylobacter -- all important causes of serious diarrheal disease worldwide.

AVANT's bacterial vaccines platform offers opportunities for development of a variety of vaccines against infectious agents that might be employed as weapons of bioterrorism. During 2004, the company received a second appropriation in the U.S. Defense budget for the development of an oral vaccine combining protection against plague and anthrax. This brings the funding for this biodefense program to \$10 million to date. AVANT plans to manufacture material for the plague portion of this vaccine in its new Fall River facility in preparation for the start of human safety studies after completion of validation work.

Financial Guidance for 2005

Revenues

For 2005, AVANT expects revenue to be between \$6-\$7 million, compared with 2004 revenue of \$6.9 million, primarily derived from government contracts and grants and from product royalties.

Research and Development

Research and development spending is expected to be between \$18-\$20 million in 2005, compared with 2004 R&D expense of \$13.6 million. The change in R&D spending from 2004 to 2005 primarily reflects three factors:

- (i) Spending on clinical trials will be increased, with the primary focus in 2005 on the completion of our Phase IIb trial of TP10 in females undergoing cardiac by-pass surgery and an oral plague vaccine scheduled for proof-of-concept testing in humans during 2005. Clinical trial costs for our bacterial vaccines program -- Phase II studies for CholeraGarde(R) in Bangladesh and a Phase I in-patient study for Ty800, will be incurred by our partners, the IVI and the NIH:
- (ii) Spending to complete the TP10 process development program by Lonza plc, our contract manufacturing partner for this compound, in preparation for the manufacture of cGMP Phase III clinical materials; and
- (iii) Costs associated with the validation and operation of our Fall River manufacturing facility for a full calendar year.

Other Operating Expenses

AVANT expects general and administrative expenses, including amortization of acquired intangible assets, this year to be in the range of \$7-\$8 million, compared with 2004 expenses of \$6.6 million.

Partnering Activities

In 2005, AVANT will actively pursue partnering opportunities for its TP10 and CETi programs, however, the timing and size of any partnering arrangement is difficult to predict.

Dr. Ryan and Mr. Catlin will host a conference call at 11:00 AM EST on Wednesday, March 2, 2005 to discuss the 2004 financial results and guidance for 2005. To access the conference call, dial 800-510-9691 (within the United States), or 617-614-3453 (if calling from outside the U.S.). The participant passcode is 85862571. An audio replay will be available immediately following 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 for the audio replay is 46354902.

The call will also be broadcast via the Company's website: www.avantimmune.com. 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.

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. Three of AVANT's products are marketed, including two food safety vaccines and 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 $% \left(1\right) =\left(1\right) \left(1\right) \left$ associated with cardiac bypass 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. Further, AVANT has established a state-of-the-art vaccine manufacturing facility for the implementation of its VitriLife(R) technology and the production of its own vaccines and other companies' products. AVANT's goal is to demonstrate proof-of-concept for its products in the clinic 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 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" "project" and similar expressions which do not relate "estimate" 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), Ty800and other products; (6) the ability of the Company to manage multiple late stage clinical trials for a variety of product candidates; (7) the volume and profitability of product sales of Megan(R)Vac 1, Megan(R)Egg and other future products; (8) the process of obtaining regulatory approval for the sale of Rotarix(R) in major commercial markets, as well as the timing and success of worldwide commercialization of Rotarix(R) by our partner, GlaxoSmithKline; (9) changes in existing and potential relationships with corporate collaborators; (10) the availability, cost, delivery and quality of clinical and commercial grade materials supplied by contract manufacturers; (11) 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; (12) the ability to obtain substantial additional funding; (13) the ability to develop and commercialize products before competitors; (14) the ability to retain certain members of management; and (15) 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.

-table follows-

AVANT IMMUNOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENTS
OF OPERATIONS DATA

OPERATING REVENUE	2004	2003	2004	2003
Product	-			
Development and				
Licensing Agreements	\$2,172,600	\$183.900	\$4,565,700	\$1,803,900
Government	<i>\$2,112,000</i>	\$100,000	ψ., 555, 160	Ψ1,000,000
Contract	100 400	624 000	2 445 222	2 664 202
Revenue Product Royalties	186,400 48,300	631,900 41,900	2,115,200 177,700	2,661,200 167,800
			,,,,	
Total Operating Revenue	2 407 200	9E7 700	6 959 600	4 622 000
	2,407,300	057,700	6,858,600 	4,632,900
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OPERATING EXPENSE Research and	<u> </u>			
Development	3,947,000	2,145,300	13,573,800	10,021,300
Cost of Revenue		-	300,000	-
General and Administrative	1,719,600	1,442,200	5.572.000	5.350.500
Amortization of	1,:10,000	1,772,200	3,3,2,000	5,555,566
Acquired	040 700	040 700	005 100	005 400
Intangible Asset	.s 248,700	248,700	995,100	995,100
Total Operating				
Expense	6,215,300	3,836,200	20,440,900	16,366,900
perating Loss	(3,808,000)	(2,978,500)	(13,582,300)	(11,734,000)
Investment and Ot	her			
Income, Net		53,700	378,600	239,800
Net loss before cumulative effe	ect of			
change in accou	ınting			
principle	(3,698,300)	(2,924,800)	(13,203,700)	(11,494,200)
Cumulative effect	ct of			
change in accou	ınting			
change in accou principle	ınting - 	-	-	(1,175,300)
principle 	-	-	-	
principle Net Loss	\$(3,698,300)		\$(13,203,700)	\$(12,669,500)
principle 	\$(3,698,300)			\$(12,669,500)
principle Net Loss Basic and Diluted	\$(3,698,300) ========			\$(12,669,500)
principle Net Loss Sasic and Diluted Loss per Common	\$(3,698,300) ===================================			\$(12,669,500)
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Principle Net Loss Basic and Diluted Loss per Common Net loss befor cumulative e of change in accounting principle Cumulative eff of change in accounting	\$(3,698,300) ==================================	(0.05)	(0.18)	\$(12,669,500)
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Net Loss Basic and Diluted Loss per Common Net loss befor cumulative e of change in accounting principle Cumulative eff of change in accounting	\$(3,698,300) ===================================	(0.05)	(0.18)	\$(12,669,500) ===================================
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LIABILITIES AND STOCKHOLDERS' EQUITY Current Liabilities \$5,450,900 \$3,385,400 Noncurrent Liabilities 1,944,900 38,407,700 27,919,700 Stockholders' Equity Total Liabilities and Stockholders' Equity \$45,803,500 \$31,305,100

CONTACT: AVANT Immunotherapeutics, Inc.

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Avery W. Catlin Chief Financial Officer

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