

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
February 24, 2004

AVANT IMMUNOTHERAPEUTICS, INC.
(Exact name of registrant as specified in charter)

Delaware (State or other jurisdiction of incorporation)	0-15006 (Commission file number)	13-3191702 (IRS employer identification no.)
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119 Fourth Avenue
Needham, Massachusetts 02494
(Address of principal executive offices) (Zip code)

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

ITEM 7. FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS.

(c) Exhibits.

99.1 The Company's Press Release dated February 24, 2004.

ITEM 9. REGULATION FD DISCLOSURE.

The following information is furnished under Item 12 of Form 8-K "Results of Operations and Financial Condition". This information is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report on Form 8-K shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933 as amended.

On February 24, 2004, the Company issued a press release which is attached to this Form 8-K as Exhibit 99.1 and incorporated herein by reference.

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 hereunto duly authorized.

AVANT IMMUNOTHERAPEUTICS, INC.

Date: February 24, 2004

By: /s/ Avery W. Catlin

Avery W. Catlin
Senior Vice President and
Chief Financial Officer

EXHIBIT INDEX

Exhibit
Number

Description

99.1

The Company's Press Release dated February 24, 2004

AVANT Reports Fourth Quarter and Fiscal 2003 Financial Results;
Provides 2004 Financial Guidance

NEEDHAM, Mass.--(BUSINESS WIRE)--Feb. 24, 2004--AVANT Immunotherapeutics, Inc. (Nasdaq: AVAN) today reported financial results for the fourth quarter and year ended December 31, 2003. The Company reported a net loss of \$2.9 million, or \$0.05 per share, for the fourth quarter of 2003 compared to a net loss of \$3.5 million, or \$0.06 per share, for the fourth quarter of 2002. The decreased loss for the fourth quarter of 2003 primarily reflects an increase in revenue combined with a decrease in operating expense compared to the same period in 2002, offset by a reduction in interest income.

The increase in revenue of \$46,900 results primarily from government contract and product royalty revenues in 2003, offset by a reduction in licensing revenue as a result of a milestone payment of \$500,000 received from Pfizer in late 2002. The decrease in operating expense of \$564,900, or 12.8%, primarily results from a reduction in research and development expenses in the fourth quarter of 2003 related to a decrease in manufacturing costs for the bacterial vaccines programs during the fourth quarter of 2003 and a decrease in consulting expenses. The decrease in research and development expenses was offset in part by an increase in clinical trials costs, facility-related expenses, personnel and related expenses and legal costs. At December 31, 2003, the Company reported cash and cash equivalents of \$20.3 million.

For the year ended December 31, 2003, the Company reported a net loss of \$12.7 million, or \$0.20 per share, compared to a net loss of \$13.8 million, or \$0.23 per share, for fiscal 2002. AVANT changed its accounting for patent costs in 2003 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 \$0.02 per share for the year ended December 31, 2003. The full year results for 2003 reflect a decrease in revenue and the cumulative effect of a change in accounting principle, offset by a decrease in operating expense compared to the same period in 2002. The decrease in revenue of \$2.1 million, or 30.9%, primarily results from the one-time recognition of approximately \$4.0 million in revenue upon the termination of the Novartis TP10 agreement in the third quarter of 2002 and the milestone payment received from Pfizer in late 2002. This was offset in part by new government contract revenue of \$2.7 million for biodefense vaccine development recorded in 2003 and the recognition of a \$1 million milestone payment from GlaxoSmithKline in the third quarter of 2003 upon initiation of Phase III clinical trials of the Rotarix(R) rotavirus vaccine. The decrease in operating expense of \$4.8 million, or 22.6%, is primarily due to decreased clinical trials costs and contract manufacturing costs incurred in connection with the company's clinical programs. It also reflects declines in personnel and related expenses, sponsored research and consultancy costs, offset partly by increases in legal, patent and facility-related expenses. The decrease in investment income of \$362,900 reflects lower average cash balances between periods and significantly lower interest rates.

"During 2003, we achieved the following notable clinical and financial milestones," said Una S. Ryan, Ph.D., President and Chief Executive Officer of AVANT Immunotherapeutics, Inc.:

- We are establishing a pilot manufacturing facility in Fall River, Massachusetts with funding assistance from MassDevelopment. This facility will implement our VitriLife(R) technology.
- The first of our products entered Phase III clinical studies as our partner, GlaxoSmithKline (GSK), began trials of Rotarix(R) in Latin America and South East Asia.
- CETi-1, our novel vaccine for cholesterol management, demonstrated proof-of-concept in humans when Phase II data showed that a vaccine approach could indeed raise HDL.
- Data from a Phase II trial showed that treatment with TP10, our novel inhibitor of complement-mediated inflammation, could reduce deaths and heart attacks in men undergoing open-heart surgery.
- Additionally, we made significant progress in applying our novel vaccine platform to the development of oral vaccines for biodefense. We have received contracts for over \$4 million of our \$8 million contract goal to support preclinical development of a single-dose, oral vaccine combining

protection from anthrax and plague.

Already in 2004, we have accomplished several additional, notable milestones:

- We announced in January 2004 positive preliminary results of the adult portion from the Phase II clinical trial in Bangladesh of AVANT's cholera vaccine, CholeraGarde(TM).
- Earlier this month we announced a financing of approximately \$25 million which provides cash balances that now exceed our currently anticipated requirements for the next two years.
- Finally, last week we announced a Phase II trial of TP10 in approximately 300 female patients undergoing cardiac surgery utilizing cardiopulmonary by-pass.

Dr. Ryan continued, "AVANT has a variety of programs in clinical development, the majority of which are supported by major companies, governmental agencies or international health organizations. We were very pleased to see the first of these programs enter Phase III testing this year -- our two-dose oral rotavirus vaccine, Rotarix(R). GSK has enrolled the majority of 60,000 infants planned in trials to be completed in 2004. GSK plans their initial Rotarix(R) launch in Mexico in 2004."

Dr. Ryan added, "We are also moving forward with development of our Fall River facility, which will implement the VitriLife(R) technology acquired last year and represents a major step forward in our efforts to build a commercial company. Having this manufacturing capability will allow us to produce our "next generation" vaccines for clinical trials, specifically the biodefense vaccines under development with the U.S. Department of Defense, DynPort Vaccine Company and the National Institutes of Health. It will also enable us to compete for further government vaccine contracts. Finally, it provides AVANT with partnering opportunities to apply our VitriLife(R) technology to other companies' products."

Clinical Development Programs

AVANT's focus is unlocking the power of the immune system to prevent and treat disease. We have assembled a broad portfolio of technologies and intellectual property that give us a strong competitive position in vaccines and immunotherapeutics. Six of AVANT's products are in clinical development. AVANT expects to make substantial progress in 2004 in advancing several of these products to the later stages of clinical development.

In the second half of 2004, AVANT expects its partner, GlaxoSmithKline, to complete Phase III global clinical studies of its investigational rotavirus vaccine, Rotarix(R), a two-dose oral rotavirus vaccine which has been shown to be helpful in preventing rotavirus gastroenteritis disease in young children.

During the fourth quarter of 2004, AVANT expects to announce results from a blinded, placebo-controlled Phase IIb study of TP10, its complement inhibitor, in approximately 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 aimed at product registration. The primary endpoint is reduction in the incidence of deaths and heart attacks during and following surgery. Data from an earlier Phase II trial showed that TP10 effectively limited harmful complement-mediated inflammation in men undergoing heart surgery involving cardiopulmonary by-pass, leading to significantly fewer post-surgical deaths and heart attacks compared to placebo-treated men. However, the researchers did not see the same benefit in the smaller number of women included in the trial.

Results in late 2003 from a CETi-1 Phase II study showed that the vaccine was well tolerated and demonstrated proof-of-concept in humans that a vaccine approach could indeed raise HDL. We are evaluating a number of possibilities for the continued development of this vaccine, including the use of new adjuvants to elicit a more robust antibody response. We expect to have CETi-1 back into the clinic within approximately twelve months.

Development of a safe, effective oral cholera vaccine is the first step in establishing AVANT's single-dose, oral bacterial vaccine franchise. During 2004, AVANT expects its partner, the International Vaccine Institute (IVI), to complete pediatric Phase II trials in Bangladesh where cholera is endemic. In addition, the National Institute of Allergy and Infectious Disease (NIAID) of the National Institutes of Health (NIH) and AVANT have entered into a cooperative agreement for the NIAID to conduct a Phase I in-patient dose ranging clinical trial aimed at demonstrating the safety and immunogenicity of

the Ty800 typhoid fever vaccine. The trial is planned for an NIAID funded clinical site using NIAID funded clinical material. The NIAID trial seeks to confirm the safety and immunogenicity of the Ty800 oral vaccine observed in an earlier physician sponsored Ty800 vaccine study. Finally, we are developing three additional bacterial vaccines against enterotoxigenic E. coli, Shigella and Campylobacter -- all important causes of serious diarrheal diseases worldwide.

The attenuated live bacteria used to create AVANT's single-dose oral vaccines can also serve as vectors for developing vaccines against other bacterial and viral diseases. By engineering key disease antigens into the DNA of the vector organisms, AVANT expects to extend the protective ability of its single-dose oral vaccines to a wide variety of illnesses. We believe our vector technologies may prove useful for improving and expanding America's vaccine arsenal against microbial agents used in war or terrorist attacks.

AVANT has partnered with the U.S. Department of Defense, DynPort Vaccines Company (DVC) and the National Institutes of Health to apply AVANT's vaccine technology to important biodefense needs. Under a series of subcontracts from DVC, the prime contractor for the department of Defense's Joint Vaccine Acquisition Program (JVAP), AVANT is developing an oral vaccine that combines protection against anthrax and plague. AVANT's plans include an oral plague vaccine scheduled for proof-of-concept testing in humans during 2004 funded by DVC. AVANT has also received research funding from the National Institutes of Health (NIH) that supports the development of single-dose oral vaccines against anthrax. Furthermore, AVANT technology is employed in an improved injectable anthrax vaccine currently in Phase I clinical testing by DVC.

Financial Guidance for 2004

Revenues

For 2004, AVANT expects revenue to be between \$5-\$6 million, compared with 2003 revenue of \$4.6 million, primarily derived from government contracts and grants.

Research and Development

Research and development spending is expected to be between \$14-\$16 million in 2004, compared with 2003 R&D expense of \$10 million. The change in R&D spending from 2003 to 2004 primarily reflects three factors:

(i) Spending on clinical trials will be increased, with the primary focus in 2004 on 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 2004. Clinical trial costs for our bacterial vaccines program -- Phase II studies for CholeraGarde(TM) 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, prior to the manufacture of cGMP commercial material; and

(iii) Costs associated with the construction and validation of our Fall River pilot manufacturing facility expected to be completed in late Q4-2004.

Other Operating Expenses

AVANT expects general and administrative expenses, including amortization of acquired intangible assets, this year to be in the range of \$6.0-\$6.5 million, compared with 2003 expenses of \$6.3 million.

Net Loss

Net loss is expected to be in the range of \$14-\$17 million this year.

Dr. Ryan and Mr. Catlin will host a conference call at 11:00 AM EST on Tuesday, February 24, 2004 to discuss the 2003 financial results and guidance for 2004. To access the conference call, dial 800-901-5213 (within the United States), or 617-786-2962 (if calling from outside the U.S.). The participant passcode is 10283488. 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 95040780.

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. Six of AVANT's products are in clinical development. These include an oral human rotavirus vaccine, 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 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. 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(TM) (Peru-15), Ty800 and other products; (4) the cost, timing, scope and results of ongoing safety and efficacy trials of TP10, CETi-1, CholeraGarde(TM) (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(TM) (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) the volume and profitability of product sales of Megan(R)Vac 1 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(TM) (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.

AVANT IMMUNOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENTS
OF OPERATIONS DATA

	Quarter Ended		Year Ended	
	December 31,		December 31,	
	2003	2002	2003	2002
OPERATING REVENUE				
Product Development and Licensing				

Agreements	\$183,900	\$810,800	\$1,803,900	\$6,412,400
Government Contract Revenue	631,900	-	2,661,200	-
Product Royalties	41,900	-	167,800	-
Product Sales	-	-	-	292,400
Total Operating Revenue	857,700	810,800	4,632,900	6,704,800
OPERATING EXPENSE				
Research and Development	2,145,300	2,809,300	10,021,300	14,708,500
Selling, General and Administrative	1,442,200	1,393,100	5,350,500	5,592,100
Cost of Product Sales	-	-	-	41,000
Amortization of Acquired Intangible Assets	248,700	198,700	995,100	795,100
Total Operating Expense	3,836,200	4,401,100	16,366,900	21,136,700
Operating Loss	(2,978,500)	(3,590,300)	(11,734,000)	(14,431,900)
Interest Income, Net	53,700	115,200	239,800	602,700
Net loss before cumulative effect of change in accounting principle	(2,924,800)	(3,475,100)	(11,494,200)	(13,829,200)
Cumulative effect of change in accounting principle	-	-	(1,175,300)	-
Net Loss	\$(2,924,800)	\$(3,475,100)	\$(12,669,500)	\$(13,829,200)
Basic and Diluted Net Loss per Common Share:				
Net loss before cumulative effect of change in accounting principle	(0.05)	(0.06)	(0.18)	(0.23)
Cumulative effect of change in accounting principle	-	-	(0.02)	-
Net Loss	\$(0.05)	\$(0.06)	\$(0.20)	\$(0.23)
Weighted Average Common Shares Outstanding				
	64,707,200	60,464,900	62,512,900	60,461,600

	December 31, 2003	December 31, 2002
Cash and Cash Equivalents	\$20,251,000	\$25,070,700
Other Current Assets	2,058,000	789,300
Property and Equipment, net	912,700	1,119,500
Intangible and Other Assets, net	8,083,400	8,253,700
Total Assets	\$31,305,100	\$35,233,200
Current Liabilities	\$3,052,100	\$3,432,600
Noncurrent Liabilities	333,300	456,200
Stockholders' Equity	27,919,700	31,344,400
Total Liabilities and Stockholders' Equity	\$31,305,100	\$35,233,200

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