

**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): **June 2, 2008**

**AVANT IMMUNOTHERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**0-15006**  
(Commission File Number)

**13-3191702**  
(IRS 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)

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))

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**Item 8.01. Other Events**

On June 2, 2008, Pfizer, Inc. and the Registrant issued a press release concerning certain data with respect to Phase 2 ACTIVATE and ACT II studies with respect to its CDX-110 product, a copy of which is attached hereto as Exhibit 99.1.

The press release referred to above contains forward-looking information about a product candidate, CDX-110, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such product candidate as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments. Other factors that might cause actual results to differ materially from those in the forward-looking statements including those set forth under the headings "Business," "Risk Factors" and Management's Discussion and Analysis of Financial Condition and Results of Operations" in each of the Registrant's Annual Report on Form 10-K, its current Reports on Form 8-K, as well as those described in its other press releases and filings with the Securities and Exchange Commission, from time to time. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences. The forward-looking statements were based on information, plans and estimates at the date of the press release, and the Registrant does not promise to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes

**Item 9.01. Financial Statements and Exhibits**

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release issued June 2, 2008.

**SIGNATURE**

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: June 2, 2008

By: /s/ Avery W. Catlin

Avery W. Catlin

Title: Senior Vice President and  
Chief Financial Officer

**EMBARGOED UNTIL 10:15 AM CDT ON MONDAY, JUNE 2, 2008**

Pfizer, Inc.  
Vanessa Aristede  
(212) 733-3784

BMC Communications  
Brad Miles (on-site)  
(917) 570-7340

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**UPDATED CDX-110 DATA IN GLIOBLASTOMA MULTIFORME  
PRESENTED AT 44<sup>th</sup> ANNUAL ASCO ANNUAL MEETING**

***Survival and Time-to-Progression Reported From Open-Label  
Phase II Studies***

**CHICAGO — June 2, 2008** — AVANT Immunotherapeutics (Nasdaq: AVAN) and Pfizer, Inc. (NYSE: PFE) today announced the presentation of new data from two Phase 2 studies at the 44th Annual Meeting of the American Society of Clinical Oncology (ASCO) for CDX-110, an investigational immunotherapeutic vaccine that targets the tumor-specific molecule epidermal growth factor receptor variant III (EGFRvIII). CDX-110 was generally well-tolerated with primary toxicity reported as local injection site reactions.

Included in the presentation were updated data from the Phase 2 ACTIVATE trial (n=21) and the continuation study, ACT II (n=23) of CDX-110 in patients with newly diagnosed EGFRvIII-positive glioblastoma multiforme (GBM).

- In the ACTIVATE study, median survival time was 26 months (95% CI: 21.6, infinity) and median time-to-progression (TTP) was 14.2 months. Median survival in a historical matched cohort was 15.2 months (17/17) (95% CI: 13.9, 20.5). (p=0.0001) with median time to progression of 7.13 months (p=0,0001). (1) No significant adverse events were seen in this study.
- Preliminary results from the ACT II study currently estimate median overall survival to be 33.1 months,

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(1) Heimberger, A., et al. *Epidermal Growth Factor Receptor VIII Peptide Vaccination Is Efficacious Against Established Intracerebral Tumors*. Clin Cancer Res Vol. 9, pp4247-4254, September 15, 2003.

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although the median has not yet been reached. The survival of a matched historical control group was 14.3 months (95% CI: 13.0, 16.2) and a subgroup treated with temozolomide (TMZ) of 15.2 months (95% CI: 13.9, 20.5 p=0.0078). Overall TTP was 16.6 months (95% CI: 10.8, infinity) compared with 6.4 months for the historical control group (95% CI: 5.0, 14.1). In this study, primary toxicity was reported as local injection site reactions.

“Vaccination with CDX-110 together with standard of care temozolomide in patients with glioblastoma multiforme increased time to progression and overall survival compared with a matched historical control group in these Phase 2 studies,” said John Sampson, M.D., Associate Professor of Neurosurgery at Duke University Medical Center, who presented the data. “This is encouraging news for patients with this specific type of brain tumor, who are currently facing very limited treatment options. This treatment is being further studied in a randomized Phase 2b/3 trial to confirm these results.”

### **Study design**

The ACTIVATE trial studied CDX-110 vaccine in 21 patients with newly-diagnosed EGFRvIII-expressing GBM who had undergone surgical (gross-total) resection followed by conformal radiation therapy with concurrent oral temozolomide (75 mg/m<sup>2</sup> per day) without tumor progression. CDX-110 mixed with granulocyte-macrophage colony stimulating factor (GM-CSF) (142 mcg) was administered intradermally. Sixteen patients received CDX-110 at two week intervals for three doses, while five patients received saline in a blinded fashion for the first three vaccinations. Thereafter, all patients received monthly CDX-110 injections mixed with GM-CSF until tumor progression. Safety was assessed through evaluation of adverse events, complete physical and neurological exams, and routine clinical laboratory studies.

The ACT II study enrolled a total of 23 patients. The patient population and treatment scheme were similar to ACTIVATE, except that no early placebo was given and two dose schedules of maintenance temozolomide were studied (13 patients received 200 mg/m<sup>2</sup> daily times five every 28 days, while 10 received 100 mg/m<sup>2</sup> daily times 21 days every 28 days for a maximum of 12 cycles). Monthly CDX-110

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vaccination mixed with GM-CSF was given on day 21 of each cycle until tumor progression. Safety was assessed in a similar fashion to ACTIVATE.

### **About EGFR vIII**

EGFRvIII is a mutated form of epidermal growth factor receptor (EGFR) that is only expressed in cancer cells and not in normal tissue(2) and is a transforming oncogene that can directly contribute to cancer cell growth, as it does in about 40 percent of GBM tumors.(3),(4),(5)

AVANT is currently enrolling the Phase 2b portion of a Phase 2b/3 clinical trial called ACT III, which is evaluating CDX-110 in 90 patients at over 20 cancer centers across North America. The Phase 3 portion will not open until data is available from Phase 2b and pending further discussions with FDA.

### **About CDX-110**

CDX-110 is an investigational immunotherapy that targets the tumor specific molecule EGFRvIII, a functional variant of the epidermal growth factor receptor (EGFR), which is a protein that has been well validated as a target for cancer therapy. This particular variant, EGFRvIII, was discovered in a collaborative effort between Bert Vogelstein, M.D. and Bigner, M.D., at Duke University. Application of this discovery toward the development of the CDX-110 vaccine was further advanced by Dr. John Sampson, M.D. and his colleagues at the Duke University Brain Tumor Center in collaboration with Amy Heimberger, M.D. at the M.D. Anderson Cancer Center. Unlike EGFR, EGFRvIII is not present in normal tissues, suggesting this target will enable the development of a tumor-specific therapy for cancer patients. Furthermore, EGFRvIII is a transforming oncogene that can directly contribute to cancer cell growth. While originally discovered in GBM, the most common and aggressive form of brain cancer, the expression of EGFRvIII has also been observed in various tumors such as

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(2) Sok C, et al. *Mutant Epidermal Growth Factor Receptor (EGFRvIII) Contributes to Head and Neck Cancer Growth and Resistance to EGFR Targeting* Clin Cancer Res; 12(17) Sept.1, 2006

(3) Heimberger A., et al. *Prognostic Effect of Epidermal Growth Factor Receptor and EGFR vIII in Glioblastoma Multiforme Patients* Clin Cancer Res Vol 11, p.1462 February 15, 2005

(4) Lund-Johansen, M., et al. *Effect of Epidermal Growth Factor on Glioma Cell Growth, Migration, and Invasion In Vitro*. Cancer Res 50, p. 6039

(5) Wikstrand C, et al. *Cell Surface Localization and Density of the Tumor-Associated Variant of the Epidermal Growth Factor Receptor, EGFRvII* Cancer Res 57, p.4130, September 15 1997

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breast, ovarian, metastatic prostate, colorectal, and head & neck cancers. Celldex owns the rights to EGFRvIII vaccines and is pursuing the development of CDX-110 for GBM therapy, as well as in other cancers through additional clinical studies.

On April 16, 2008, Pfizer, Inc. and Celldex Therapeutics, a wholly-owned subsidiary of AVANT Immunotherapeutics, entered into an agreement that granted Pfizer an exclusive worldwide license to CDX-110.

### **About Glioblastoma Multiforme**

GBM is the most common form of primary brain tumor. It is an aggressive tumor with very poor prognosis.(6) There are an estimated 10,000 new cases of GBM annually in the United States, and it predominantly affects adults aged 45 to 70. Current GBM treatment options include surgical resection, radiotherapy and chemotherapy.

### **About AVANT Immunotherapeutics, Inc.**

AVANT Immunotherapeutics is a NASDAQ-listed company discovering and developing innovative vaccines and targeted immunotherapeutics for the treatment of cancer, infectious and inflammatory diseases. AVANT focuses on the use of tumor-specific targets and human monoclonal antibodies (mAbs) to precisely deliver therapeutic agents through its novel “targeted immunization” approach. In addition, AVANT is exploiting its access to proprietary human antibody technology for development of therapeutic monoclonal antibodies (mAbs). AVANT’s deep product pipeline consists of products in varying stages of development. AVANT’s lead product, CDX-110, is an immunotherapy that targets the variant III (vIII) mutation of the epidermal growth factor receptor (EGFR). Additional information on AVANT’s pipeline can be obtained through the Company’s web site at <http://www.avantimmune.com>.

### **About Pfizer Oncology**

Pfizer Oncology is committed to the discovery, investigation and development of treatments and currently has 22 innovative compounds in clinical development across four platforms. By leveraging the strength of our resources

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(6) Uddin S, Jarmi T. *Glioblastoma Multiforme*. Available at <http://www.emedicine.com/NEURO/topic147.htm>. Accessed May 6, 2008.

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and scientific talent, Pfizer Oncology strives to discover and develop novel treatment options to improve the outlook for oncology patients. Pfizer currently devotes more than 22 percent of its total R&D budget to the field of oncology, investing annually in worldwide research initiatives. We also partner with healthcare providers, governments and local communities around the world to provide better quality healthcare and health system support. For more information on the above information, please visit <http://www.pfizer.com>.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of June 2, 2008. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a product candidate, CDX-110, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such product candidate as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and in its reports on Form 10-Q and Form 8-K.

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