# 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): April 15, 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:

- o 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 1.01. Entry into a Material Definitive Agreement

On April 16, 2008, Celldex Therapeutics, Inc. ("Celldex"), a wholly-owned subsidiary of AVANT Immunotherapeutics, Inc., a Delaware corporation (the "Registrant"), entered into a License and Development Agreement (the "License and Development Agreement") with Pfizer Vaccines, LLC ("Pfizer Vaccines"). At the closing of the transactions described in the License and Development Agreement, the Registrant will enter into a Common Stock Purchase Agreement with Pfizer Vaccines (the "Common Stock Purchase Agreement").

Under the License and Development Agreement, Celldex has granted to Pfizer Vaccines an exclusive worldwide license to Celldex's therapeutic cancer vaccine candidate, CDX-110, in Phase 2 development for the treatment of glioblastoma multiforme (GBM). CDX-110, which has been granted both Fast Track and Orphan Drug designations by the U.S. Food and Drug Administration (FDA), 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. The License and Development Agreement also gives Pfizer Vaccines exclusive rights to the use of EGFRvIII vaccines in other potential indications.

Under the License and Development Agreement, Pfizer Vaccines will make an upfront payment to Celldex of \$40 million and, through the Common Stock Purchase Agreement, will purchase \$10 million of the Registrant's common stock at a price per share which represents a 25% premium to the average daily closing price of the Registrant's common stock for the five trading days immediately preceding April 16, 2008. Further, Pfizer Vaccine will fund all development costs for CDX-110 and other EGFRvIII programs under the License and Development Agreement. Celldex is also eligible to receive milestone payments exceeding \$390 million for the successful development and commercialization of CDX-110 and additional EGFRvIII vaccine products, as well as double-digit royalties on any product sales.

The License and Development Agreement is subject to approval under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (as amended) and is expected to close in the second quarter of 2008. The common stock purchase will close simultaneously with the closing of the License and Development Agreement.

Under the terms of the Common Stock Purchase Agreement, the Registrant will grant to Pfizer Vaccines piggyback registration rights, and demand registration rights on Form S-3 (no more than twice during any twelve-month period in the case of demand registration on Form S-3). These registration rights would expire upon the earlier of the sale of all of the common stock subject to those rights, or the fifth anniversary of the date of the Common Stock Purchase Agreement, and are not assignable by Pfizer Vaccines except to an affiliate of Pfizer Vaccines. Pfizer Vaccines has agreed to refrain from selling the shares of common stock purchased under the Common Stock Purchase Agreement for one year after signing the Common Stock Purchase Agreement, provided that it can sell up to 10% of such shares of common stock during any rolling 90-day

period from and after the six-month anniversary of the signing of that agreement. Pfizer Vaccines will also be subject to a limited standstill agreement with the Registrant for a period of 18-months following the signing of the Common Stock Purchase Agreement.

In connection with the License and Development Agreement, Celldex also entered into agreements amending its existing license agreements with Duke University and Thomas Jefferson University relating to license and other rights to Celldex's vaccines, as well as milestone and royalty payments.

The Registrant and Pfizer, Inc., an affiliate of Pfizer Vaccines, have a pre-existing business relationship apart from the License and Development Agreement. In connection with the Registrant's acquisition of Megan Health in 2000, the Registrant entered into a licensing agreement with Pfizer, Inc. whereby Pfizer, Inc. licensed Megan Health's technology for the development of animal health and food safety vaccines. Upon execution of the agreement, Pfizer made an initial license payment of \$2.5 million together with a \$3 million equity investment. In December 2002, the Registrant received a milestone payment of \$500,000 from Pfizer, Inc. as a result of the submission of an application with the USDA for licensure of a food safety vaccine. Under the Megan Health agreement with Pfizer, Inc., the Registrant may receive additional milestone payments of up to \$3 million based upon attainment of specified milestones.

On April 16, 2008, the Registrant issued a press release concerning the transaction with Pfizer Vaccines, a copy of which is attached hereto as <a href="Exhibit 99.1">Exhibit 99.1</a>.

#### Item 3.02. Unregistered Sales of Equity Securities

On the effective date of the transactions described in the License and Development Agreement, the Registrant will enter into the Common Stock Purchase Agreement with Pfizer Vaccines, whereby the Registrant will sell 780,944 shares of the Registrant's common stock, at a price per share of \$12.81, to Pfizer Vaccines, for aggregate cash consideration to the Registrant of \$10,000,000. The sale of the shares of common stock will not be registered under the Securities Act of 1933. Rather, the offer of such shares was, and sale of such shares will be, made in reliance on the exemption from registration requirements provided by Section 4(2) of the Securities Act and Regulation D promulgated thereunder. Pfizer Vaccines is "accredited" (as defined under Regulation D) and no general solicitation was or is being used in connection with the offer and sale of such securities.

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#### Item 8.01. Other Events

On April 15, 2008, the Registrant issued a press release concerning certain data with respect to a Phase 2 ACT II study with respect to its CDX-110 product, a copy of which is attached hereto as <u>Exhibit 99.2</u>.

#### Item 9.01. Financial Statements and Exhibits

Exhibit		Description	
99.1	Press Release issued April 16, 2008.		
99.2	Press Release issued April 15, 2008		
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#### **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: April 17, 2008 By: /s/ Avery W. Catlin

Avery W. Catlin Title: Senior Vice President and Chief Financial Officer

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For Immediate Release: April 16, 2008

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## PFIZER AND AVANT ENTER INTO LICENSING AND DEVELOPMENT AGREEMENT FOR NOVEL THERAPEUTIC VACCINE CANDIDATE FOR BRAIN CANCER

NEW YORK and NEEDHAM, MA (April 16, 2008) – Pfizer, Inc. (NYSE: PFE) and AVANT Immunotherapeutics (Nasdaq: AVAN), acting through its wholly-owned subsidiary Celldex Therapeutics, Inc. today announced that they have entered into an agreement under which Pfizer will be granted an exclusive worldwide license to a therapeutic cancer vaccine candidate, CDX-110, in Phase 2 development for the treatment of glioblastoma multiforme (GBM). This agreement also gives Pfizer exclusive rights to the use of EGFRvIII vaccines in other potential indications.

CDX-110, which has been granted both Fast Track and Orphan Drug designations by the U.S. Food and Drug Administration (FDA), 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 in certain tumor types.

EGFRvIII is only expressed in cancer cells and not in normal tissue and is a transforming oncogene that can directly

contribute to cancer cell growth, as it does in about 40 percent of GBM tumors.

"We are excited about the potential for CDX-110 and intend to partner with AVANT and academic physician-scientists to investigate this novel vaccine candidate with the hope of providing patients and doctors with a new treatment option for this devastating disease," said Dr. Briggs Morrison, Senior Vice President for Clinical Development at Pfizer.

Under the licensing and development agreement, Pfizer will make an upfront payment to AVANT of \$40 million and will make a \$10 million equity investment in AVANT. Pfizer will fund all development costs for these programs. AVANT is also eligible to receive milestone payments exceeding \$390 million for the successful development and commercialization of CDX-110 and additional EGFRvIII vaccine products, as well as double-digit royalties on any product sales. The agreement is subject to approval under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (as amended) and is expected to close in the second quarter of 2008.

"This partnership advances the therapeutic potential for CDX-110, particularly for patients with GBM. We are very pleased to initiate this relationship to expand our clinical development activities for GBM and toward other cancers," said Ron Newbold, Ph.D., Senior Vice President of Business Development of AVANT Immunotherapeutics. Una Ryan, CEO of AVANT, added, "We see this as an important milestone for the immunotherapy field, and we look forward to Pfizer's commitment to help even more cancer patients in the future."

CDX-110 is designed to induce or enhance the body's immune responses against EGFRvIII resulting in destruction of tumor cells that express the variant receptor. Early efficacy and

safety data from single arm Phase 2 clinical trials of CDX-110 in combination with the current standard treatment for patients with GBM are very encouraging. Progression-free survival and overall survival data from these trials compare very favorably with historical control data. A randomized Phase 2 trial is ongoing.

GBM is the most common and aggressive form of primary brain tumor, with very poor prognosis. There are an estimated 10,000 new cases of GBM annually in the United States, which predominantly affects adults aged 45 to 70. The current standard treatment for patients with GBM includes surgical resection, radiotherapy with concurrent temozolomide and then adjuvant temozolomide chemotherapy.

#### **About Pfizer Inc**

Pfizer discovers and develops innovative medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality healthcare and health system support.

#### About AVANT Immunotherapeutics, Inc.

AVANT Immunotherapeutics and Celldex Therapeutics combined during the first quarter of 2008. AVANT 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. Identification of the potential of EGFRvIII in

cancer diagnosis, prevention and therapy was based on the collaborative efforts of Dr. Bert Vogelstein and Dr. Albert Wong at Johns Hopkins University and Dr. Darell Bigner at Duke University. Application of this discovery toward the development of the CDX-110 vaccine was further advanced by Dr. John Sampson and his colleagues at the Duke University Brain Tumor Center in collaboration with Dr. Amy Heimberger at the MD Anderson Cancer Center. AVANT also has several product candidates in its development pipeline including:

- · CDX-1307, a product based on its proprietary APC Targeting Technology<sup>™</sup>, which is in two Phase 1 clinical trials for patients with advanced pancreatic, bladder, breast and colon cancer;
- · TP10, a complement inhibitor, in development for transplantation and other indications; and
- · Three candidates based on its oral, rapidly-protecting, single-dose and temperature-stable vaccine technology, including combination vaccines for travelers, the military and global health needs.

AVANT has three commercialized products, including Rotarix® (partnered with GSK) for the prevention of rotavirus infection and two human food safety vaccines for reducing salmonella infection in chickens and eggs. Additional information on AVANT Immunotherapeutics, Inc. can be obtained through its web site http://www.avantimmune.com.

For more information on Pfizer or AVANT please visit www.pfizer.com or www.avantimmune.com

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PFIZER DISCLOSURE NOTICE: The information contained in this release is as of April 16, 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 license agreement between Pfizer Inc. and AVANT Immunotherapeutics relating to a therapeutic cancer vaccine candidate, CDX-110, and other potential vaccines and the potential benefits thereof. This information involves substantial risks and uncertainties including, among other things, the satisfaction of the condition to closing the agreement; the uncertainties inherent in research and development activities; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for CDX-110 and other potential vaccines as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential thereof; and competitive developments.

A further list and 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.

AVANT DISCLOSURE NOTICE: Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995: This release includes forward-looking statements that are subject to a variety of risks and uncertainties and reflect AVANT's current views with respect to future events and financial performance. There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by AVANT. These factors include, but are not limited to: (1) the successful integration of the business post-merger, multiple technologies and programs; (2) the ability to adopt AVANT's APC Targeting Technology<sup>TM</sup> to develop new, safe and effective vaccines against oncology and infectious disease indications; (3) the ability to adapt AVANT's vectoring systems to develop new, safe and effective orally administered vaccines against disease causing agents; (4) the ability to successfully complete product research and further development, including animal, pre-clinical and clinical studies, and commercialization of CDX-110, CDX-1307, CholeraGarde® (Peru-15), Ty800, ETEC E. coli vaccine, and other products and AVANT's expectations regarding market growth; (5) the cost, timing, scope and results of ongoing safety and efficacy trials of CDX-110, CDX-1307, CholeraGarde® (Peru-15), Ty800, ETEC E. coli vaccine and other preclinical and clinical testing; (6) the ability to negotiate strategic partnerships or other disposition transactions for AVANT's cardiovascular programs, including TP10 and CETi; (7) the ability of AVANT to manage multiple clinical trials for a variety of product candidates; (8) the volume and profitability of product sales of Megan<sup>®</sup>Vac 1, Megan<sup>®</sup>Egg and other future products; (9) the process of obtaining regulatory approval for the sale of Rotarix<sup>®</sup> in major commercial markets, as well as the timing and success of worldwide commercialization of Rotarix<sup>®</sup> by our partner, GlaxoSmithKline or Glaxo; (10) Glaxo's strategy and business plans to launch and supply Rotarix<sup>®</sup> worldwide, including in the U.S. and other major markets and its payment of royalties to AVANT; (11) AVANT's expectations regarding its technological capabilities and expanding its focus to broader markets for vaccines; (12) changes in existing and potential relationships with corporate collaborators; (13) the availability, cost, delivery and quality of clinical and commercial grade materials produced at AVANT's own manufacturing facility or supplied by contract manufacturers and partners; (14) the timing, cost and uncertainty of obtaining regulatory approvals; (15) AVANT's ability to develop and commercialize products before competitors that are superior to the alternatives developed by

such competitors; (16) AVANT's ability to retain certain members of management; (17) AVANT's expectations regarding research and development expenses and general and administrative expenses; (18) AVANT's expectations regarding cash balances, capital requirements, anticipated royalty payments (including those from Paul Royalty Fund), revenues and expenses, including infrastructure expenses; (19) the ability to obtain substantial additional funding; (20) AVANT's belief regarding the validity of our patents and potential litigation; (21) Pfizer's and our strategy and business plans concerning the continued development and commercialization of CDX-110; and (22) certain other factors that might cause AVANT's 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 AVANT's Annual Report on Form 10-K, its current Reports on Form 8-K, as well as those described in AVANT's 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. These forward-looking statements were based on

#### FOR IMMEDIATE RELEASE/April 15, 2008

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Significant Tumor-Specific Immune Response Observed in AVANT's Phase 2 Trial Evaluating CDX-110 with Temozolomide for Treatment of Glioblastoma Multiforme

- New Data Subject of Late-Breaking Presentation at American Association for Cancer Research Meeting -

**NEEDHAM, MA (April 15, 2008):** Celldex Therapeutics (a wholly-owned subsidiary of AVANT Immunotherapeutics, Nasdaq: AVAN) announced today that new data from the Phase 2 ACT II study in glioblastoma multiforme (GBM) suggest that temozolomide, the standard chemotherapy agent for this disease, may potentiate the effect of AVANT's vaccine candidate CDX-110. These data were presented in a late-breaking presentation at the annual meeting of the American Association for Cancer Research (AACR) in San Diego, California.

All patients vaccinated with CDX-110 in the Phase 2a ACT II extension study showed a tumor-specific immune response, a significant improvement over previous vaccines and over CDX-110 alone. Patients vaccinated in conjunction with the daily temozolomide (TMZ) dose had a statistically significant increase in anti-EGFRvIII antibody titers (P=0.028) compared to patients that received the standard 200 mg/m<sup>2</sup> dose of TMZ. In addition, the Delayed Type Hypersensitivity response (DTH) following vaccination was also greater in the patients receiving the continuous 21 day TMZ dose (P=0.05). Early Time to Progression (TTP) and Overall Survival (OS) data also look very promising. Contrary to conventional scientific expectation, these data suggest that chemotherapy enhances the induction of a vaccine specific immune response, and that daily chemotherapy may further enhance the vaccine's effect.

"These fascinating results may represent a new paradigm in tumor vaccine therapy," said John Sampson, M.D., a Neurosurgeon at Duke University and the lead investigator of the study. "If we can combine the tumor killing effect of chemotherapy with an enhanced effect from tumor specific immunotherapy, we may be entering a new era for GBM treatment." Tom Davis, AVANT's Chief Medical Officer, added, "We are very pleased to see ongoing data confirm our belief that CDX-110 plus TMZ may improve the prognosis for patients with GBM and expect to

present survival data from this study at ASCO in June. We also eagerly await the data from AVANT's currently enrolling randomized Phase 2b/3 study, ACT III, which is designed to confirm the Phase 2a results."

#### The Study

Dr. John Sampson and colleagues have previously generated data in the Phase 2a ACTIVATE study suggesting that the CDX-110 vaccine given alone in the adjuvant setting could lead to a doubling of survival in patients with newly diagnosed, resected GBM that expresses EGFRvIII, a proprietary tumor specific variant of the EGFR protein. Traditional scientific thought would suggest that chemotherapy, particularly if given daily, would undermine the effect of a vaccine. Based upon preclinical data suggesting that temozolomide (TMZ), a standard treatment for GBM, might actually improve the effect of CDX-110, Dr. Sampson enrolled 21 patients in the ACT II study. Patients received CDX-110 along with adjuvant temozolomide on either a monthly or daily regimen, and were followed for immune responses, Time to Progression (TTP) and Overall Survival (OS).

#### **About the CDX-110 Vaccine**

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 Dr. Bert Vogelstein and Dr Albert Wong at Johns Hopkins University and Dr. Darell Bigner at Duke University. 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 Glioblastoma Multiforme (GBM), the most common and aggressive form of brain cancer, the expression of EGFRvIII has also been observed in various other cancers such as breast, ovarian, metastatic prostate, colorectal, and head & neck malignancies. AVANT has exclusive worldwide 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.

#### About AVANT Immunotherapeutics, Inc.

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Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995: This release includes forward-looking statements that are subject to a variety of risks and uncertainties and reflect AVANT's current views with respect to future events and financial performance. There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by AVANT. These factors include, but are not limited to: (1) the successful integration of the business post-merger, multiple technologies and programs; (2) the ability to adopt AVANT's APC Targeting Technology<sup>TM</sup> to develop new, safe and effective vaccines against oncology and infectious disease indications; (3) the ability to adapt AVANT's vectoring systems to develop new, safe and effective orally administered vaccines against disease causing agents; (4) the ability to successfully complete product research and further development, including animal, pre-clinical and clinical studies, and commercialization of CDX-110, CDX-1307, CholeraGarde® (Peru-15), Ty800, ETEC E. coli vaccine, and other products and AVANT's expectations regarding market growth; (5) the cost, timing, scope and results of ongoing safety and efficacy trials of CDX-110, CDX-1307, CholeraGarde® (Peru-15), Ty800, ETEC E. coli vaccine and other preclinical and clinical testing; (6) the ability to negotiate strategic partnerships or other disposition transactions for AVANT's cardiovascular programs, including TP10 and CETi; (7) the ability of AVANT to manage multiple clinical trials for a variety of product candidates; (8) the volume and profitability of product sales of Megan®Vac 1, Megan®Eqq and other future products; (9) the process of obtaining regulatory approval for the sale of Rotarix® in major commercial markets, as well as the timing and success of worldwide commercialization of Rotarix® by our partner, GlaxoSmithKline or Glaxo; (10) Glaxo's strategy and business plans to launch and supply Rotarix<sup>®</sup> worldwide, including in the U.S. and other major markets and its payment of royalties to AVANT: (11) AVANT's expectations regarding its technological capabilities and expanding its focus to broader markets for vaccines; (12) changes in existing and potential relationships with corporate collaborators; (13) the availability, cost, delivery and quality of clinical and commercial grade materials produced at AVANT's own manufacturing facility or supplied by contract manufacturers and partners; (14) the timing, cost and uncertainty of obtaining regulatory approvals; (15) AVANT's ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors; (16) AVANT's ability to retain certain members of management; (17) AVANT's expectations regarding research and development expenses and general and administrative expenses; (18) AVANT's expectations

regarding cash balances, capital requirements, anticipated royalty payments (including those from Paul Royalty Fund), revenues and expenses, including infrastructure expenses; (19) the ability to obtain substantial additional funding; (20)AVANT's belief regarding the validity of our patents and potential litigation; and (21) certain other factors that might cause AVANT's 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 AVANT's Annual Report on Form 10-K, its current Reports on Form 8-K, as well as those described in AVANT's 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. These forward-looking statements were based on information, plans and estimates at the date of this press release, and AVANT does not promise to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.