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### FDA News Lifts Dendreon after PIPEs Finance R&D

After using PIPE financings and secondary offerings to survive years of almost no income, immune response researcher Dendreon Corp. received news from the Food and Drug Administration that drove the company's stock up 147% in one day's trading.

Dendreon shares closed at \$5.22 on March 28, and trading was halted for the entirety of March 29, when an FDA panel was meeting to discuss Provenge, Dendreon's treatment for prostate cancer. All 17 members of the panel voted to acknowledge that the drug is reasonably safe, and 13 of the members voted to recognize "substantial evidence" that it demonstrated efficacy in human trials.

Dendreon's shares opened at \$17.92 the next day and traded as high as \$18.05 before closing at \$12.93, almost one-and-a-half times the price where they finished the last trading session.

The Sipuleucel-T compound, trademarked under the name Provenge, is an antigen designed to generate an immune response to fight prostate cancer. The study reviewed by the FDA followed 127 prostate cancer patients treated with Provenge or a placebo. While it was not clear that the medication slowed the progress of the cancerous cells, subjects treated with the medication lived an average of 4.5 months longer than those who received placebos. Another trial involving 500 subjects is ongoing, but results will not be in until 2010.

Dendreon made its license application to the FDA in November of last year. The administration granted priority review status for the medication, and is scheduled to announce by May 15 whether Dendreon can begin marketing the medication.

"There's basically three potential outcomes" of the FDA decision, says Paul Latta, an analyst who covers Dendreon at McAdams Wright Ragen. "Either it's approved, which means it goes on the market relatively soon, or it's rejected, which means it never goes to market. Or there's the third, that it's approvable subject to the completion of further clinical trials."

Latta says the panel's recent endorsement makes flat-out disapproval unlikely. But if the FDA decides to request more data, it could wait for the end of the ongoing trial in 2010 or accept interim data somewhere in between.

Dendreon was founded in 1992 and began Phase III clinical trials for Provenge in 2000. The company also made its initial public offering of stock that year, selling shares at \$10 each to raise \$45 million. The IPO was underwritten by Prudential Vector Healthcare, SG Cowen, and Pacific Growth Equities.

A number of other medications are in Dendreon's development pipeline, but the company has not marketed any of them. Dendreon's revenues have been dwarfed by research and development costs. The company generated gross revenue of \$210,000 in 2005 and \$273,000 in 2006. Net losses those years were \$81.5 million and \$91.6 million.

Dendreon raised \$2 million through a PIPE in 2002 and \$30.75 million from another in 2003, when Morgan Stanley, **BayStar Capital**, and Mazama Capital invested in the company. At the end of the third quarter of 2006, Dendreon had cash and cash equivalent assets totaling \$34.6 million. Then the company raised \$45 million in a November placement of common stock arranged by Credit Suisse and Lazard, with shares priced at \$4.55 each.

Dendreon reported \$107.9 million in cash, cash equivalents, and short-term investments on its most recent balance sheet. The company may need these assets to fund efforts to distribute Provenge, which is aimed at a potentially lucrative but highly competitive market where many other researchers are working hard to find effective treatments.

Only days after Dendreon announced the FDA panel vote, Cell Genesys, another PIPE-financed company that Dendreon identifies as a competitor, announced updated Phase II test results for its own prostate cancer drug. The announcement appeared to show that subjects of Cell Genesys's clinical trial survived longer, on average, than those in Dendreon's test.

Cell Genesys shares rose about 31% to close at \$5.66 on Tuesday after the Phase II results were announced.

Source: Dendreon

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