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Cancer results fuel interest in Northwest Biotherapeutics

Bethesda biotech focuses on personalized vaccines

BY ROBERT RAND
STAFF WRITER

The DCVax personalized cancer vaccine developed by **Northwest Biotherapeutics** of Bethesda has received a big thumbs-up in a new report, spiking interest from potential investors and collaborators.

Publicly traded Northwest "has generated some of the most striking data on survival and delayed time to progression in both brain cancer and prostate cancer that we have seen from any product in the market or in clinical development," wrote pharmaceuticals and biotech analyst Navid Malik of the Matrix Group in London. DCVax has a "competitive advantage ... versus virtually all of the other personalized cancer vaccine players."

The report "has been very helpful," said Linda Powers, Northwest's chairwoman and managing director and co-founder of Toucan Capital of Bethesda. Together, Powers and Toucan have been majority owners of Northwest since 2004, when the company moved from Seattle, where it was founded in 1996.

"We had already had some overture from other companies in the wake of the Dendreon approval who were looking for the 'next Dendreon,'" she said, referring to the Food and Drug Administration's recent approval of Dendreon's Provenge vaccine for prostate cancer.

"There are just a few companies positioned in the landscape to be that," Powers said, adding that Malik's report, "with his well-known track record, is a significant additional boost."

Northwest has received some "very nice inquiries" from both "pharmaceutical and financial players, too," whom she declined to name.

With sales of cancer vaccines potentially reaching $3.1 billion by 2015, according to research company Datamonitor, Northwest could be attractive takeover target.

But Powers said Northwest, with a "robust" pipeline that includes potential vaccines for a number of cancers, is seeking partners, not an acquisition.

The DCVax works by using the patient's dendritic cells, which she called "the general of the army," to mobilize the "foot soldiers," such as T-cells, to fight the cancer.

Northwest will need about $10 million to complete the brain cancer clinical trial, its top focus. Once funding is secured, the trial itself could finish in 18 months, she said. That's quick for cancer treatment trials, which can "drag on for many years."

"Brain cancer kills so fast, so a clinical trial is really fast," she said. "It's a very sad reason for the trial being so fast."

Malignant brain tumors often recur within seven months of their removal, and "in 14 months, you're dead," Powers said. "We saw that with Ted Kennedy and he had access to every medical treatment on the planet."

Malik reported that results from the trial of DCVax treatment for brain cancer are "highly impressive" and survival data for prostate cancer have been "exceptional." He compared the prostate results with those of Dendreon's Provenge vaccine. Patients in trials receiving DCVax had a median survival of 38.7 months, versus 25.9 months for Provenge. Also, 64 percent of patients receiving DCVax survived three years, versus 34 percent for Provenge.

Northwest said it has received FDA approval to begin a phase 3 clinical trial of DCVax for prostate cancer in the U.S.

The company, with only four full-time employees, historically has little cash on hand — $300,000 as of May 5, according to a regulatory filing.

"We're financed on a pay-as-you-go, on an as-needed basis," Power said. "Rather than a big multimillion-dollar round, we have mostly rolling funding as needed."

During the recent recession, the company relied on debt financing. But this year, markets have begun to recover, Powers said, and Northwest has been able to secure equity financing. In its 14-year history, the company has incurred a cumulative net loss of $150.9 million, according to a regulatory filing.

Its small work force "reflects a new business model, which we're seeing more in biotechnology," she said. "Everything is done on contract services, for manufacturing and research for managing clinical trials and sites for specific projects."

All told, she estimated the company has about three dozen full-time equivalent positions on a contract basis.

"If that was all internal, the burn rate would be a killer," she said.

In other Maryland bioscience industry news:

The Government Accountability Office has rejected a protest filed by **Emergent BioSolutions** of Rockville against a federal contract modification worth up to $78.4 million that was awarded to a biodefense competitor, **PharmAthene** of Annapolis.

PharmAthene had been awarded the contract to help develop its next-generation anthrax vaccine, SparVax. Emergent claimed that the modification was "beyond the scope of the original contract, and thus amounted to an improper sole-source award to PharmAthene," according to the GAO ruling.

Following the GAO ruling, the Biomedical Advanced Research and Development Authority has notified PharmAthene to resume work on the vaccine, the company reported.

"We are very pleased by the GAO's decision, which confirms that BARDA had acted reasonably, in compliance with applicable legal and contractual requirements in its decision to enter into the modification with PharmAthene," said interim CEO Eric I. Richman in a statement. " ... the additional funding provided under the contract modification will support advanced development initiatives for SparVax through 2012."

Meanwhile, Emergent reported that it has completed deliveries of its anthrax vaccine to several nations. The sales of BioThrax, the only FDA-licensed anthrax vaccine, totaled $2.3 million in the second quarter.

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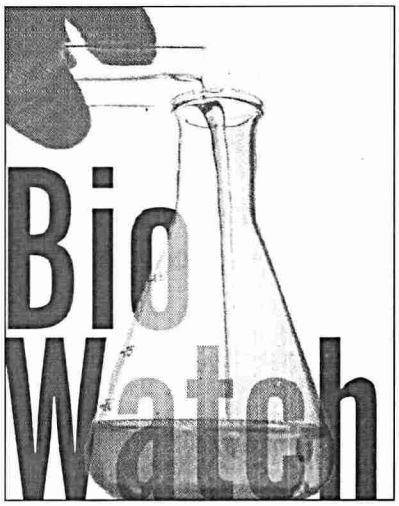

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