

Report in AMA journal excites Protein Sciences

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MERIDEN —During the peak of the flu shot shortage of 2004-05, the president of Protein Sciences Corp. tested his company's flu shot — on himself.

The insect-cell-based FluBlok had recently been through clinical studies showing it was effective, safe and reliable, even more so than the chicken-egg-based technology currently on the market.

Confident of its success, company President Daniel Adams proved that nothing would leave the Research Parkway door without being tested on him first.

Yet despite FluBlok's promise, it was still difficult for small bioscience companies to get recognition and funding to complete testing for federal licenses and to manufacture their vaccines.

On Wednesday, Protein Sciences got a booster shot — so to speak — when the results of the 2004-05 FluBlok trial were published in the prestigious *Journal of the American Medical Association*.

According to lead author Dr. John Treanor of the University of Rochester Medical Center, FluBlok vaccine protected people against the flu with few side effects.

"It serves as a validation for

the work we are doing," said Joseph Rininger, director of business development for Protein Sciences. "The pure science shows the vaccine is truly able and capable of doing what it set out to do.

The study was conducted at three sites and consisted of 460 adults who were each given one of two doses of FluBlok or a placebo during the flu season. The higher dose of FluBlok, selected as the commercial dose, showed 100 percent protection against flu.

The study also showed the vaccine safe, with the tested adults reporting symptoms similar to egg-based vaccines — sore arms. But it's less susceptible to contamination.

FluBlok has moved deeper into Phase III clinical trials, and in the fall will be tested on 4,000 study subjects in its last test before being submitted for federal Food and Drug Administration approval. Protein Sciences sold the technology last August to UMN Pharma, which has since gotten FluBlok licensed in Japan.

Wednesday's report should pique interest in this country, Adams said.

"I think a lot of people don't pay attention to results until you get it published in a major journal," Adams said. "There is a lot in the *JAMA*, but we happen to be the one that has some amazing stuff. It's the right

time, right place."

Protein Sciences is firming up agreements with potential U.S. manufacturers and Adams is confident, they will be on board when FluBlok is finally licensed.

Ongoing studies shows FluBlok offering greater protection than competing vaccines in adults over age 65, Adams said, which could provide marketing opportunities. Once the vaccine is approved, Protein Sciences will seek out patients who can derive the best value from it, he said.

The company is also using its cell-based technology on vaccines to protect against avian bird flu and SARS. Because it doesn't rely on chicken eggs to develop, the technology is less subject to contamination and quicker to make in the event of a pandemic, he said.

Adams had hoped to build a manufacturing plant at the company's research/development building on Research Parkway, but capital in small bioresearch companies has been slow to come, and the state has been reluctant to invest without significant collateral.

"We'd love to see the state get in the game," Adams said. "But we're optimistic, and things are looking great here."

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