WisBusiness.com - FluGen Works Toward Role in Fighting Flu Outbreaks

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By Brian E. Clark For WisBusiness.com

No one knows how deadly the H1N1 flu pandemic will be – if and when it spreads this fall and winter. It has killed 200 nationwide and five in Wisconsin so far. The federal Centers for Disease Control and the World Health Organization have warned it could be exceedlingly dangerous.

“It’s spreading fast,” says Paul Radspinner, president and CEO of FluGen, a fledgling Madison company.

Though Radspinner’s company does not yet have any products on the market, he hopes that within a few years, it will be able to play a major role in combating flu outbreaks. His firm is focused, he said, on the development, the production and the delivery of flu vaccines. Down the road, FluGen hopes to expand into other anti-infective products.

Of the H1N1 flu, he says, “it could be weaker than it has been,” said Radspinner of the current version of the flu, which was first detected this winter in Mexico. “Or it could recombine with the ‘bird flu’ that kills more than 60 percent of the people who get it. Not to be an alarmist, but that is a possibility and nobody knows which way it will go. “We’ll have to wait to find out. But make no mistake, this is serious and it could move very rapidly through populations. It’s pervasive and people will have a much higher risk of getting the disease.”

Radspinner founded FluGen in 2007 with Yoshi Kawaoka, a UW-Madison professor and one of the world’s top flu experts. A third co-founder is Gabi Neumann, who works with Kawaoka at the UW Influenza Viral Research Institute. FluGen now has 10 employees. He called the company “a great example of the excellent partnership between the university and people with the appropriate business experience.”

He said FluGen is the kind of enterprise that shows that biotech has a strong future in Wisconsin. “This will be a future industry that will separate us from a lot of other places,” he said. “We are happy to be a part of that and think we’ll be quite successful.”

Radspinner, a former pharmaceutical company and WARF executive, said the flu vaccine market is estimated to be about $6 billion. “We are looking at new vaccines that we think will improve the efficacy in patients – particularly the elderly – in terms of keeping them safe,” he said. “It’s not widely known, but the effectiveness of flu vaccines for that older population is as low as 20 to 40 percent.”

He said FluGen’s “microneedle” delivery device should be able to get efficacy rates of up to 80 percent among the population that is 65 or older. “That is the group that often dies from the flu,” he said. “They are the ones who have complications. They are also 40 percent of the market.” With the FluGen device, multiple needles pierce the skin and go into the dermal layer above the fat tissue and muscle. This technique, he said, delivers a

“much more robust” effect, especially for the elderly and those with compromised immune systems.

On the production side, he said FluGen has some cells that are quite good at producing flu vaccines. “The reason that’s important is because all flu vaccines are produced in embryonated (fertilized) chicken eggs. Now it takes one egg to produce one vaccine. There are millions of eggs that have to be used to produce vaccines.”

Radspinner said the technique using eggs is flawed because it is prone to contamination and quite time consuming. “There was a shortage of flu vaccine back in 2004 and part of the reason was because of contamination due to that process,” he said. “But we have a way to do it where we can use cells and cell culture to produce those vaccines. “We can do it much faster and make much more material so we won’t run out of vaccine as we have in the past. Certainly at times like these with a pandemic, we could produce a lot more vaccine, do so in a much smaller space and for less cost.”

Radspinner said the system using cells is now working at a reduced level. He said his company is now in the process of scaling up. “The FDA is very cautious with vaccines – as they should be – because millions of people will get them,” he said. “We think the FDA will be very interested in our technology because it uses cells that they are quite familiar with. Safety issues are very low. So we think it will be a couple of years before we will be up to full speed. And that also depends on whether we partner with an existing company.”

Similarly, he said it may take some time to get the microneedle device into the marketplace. “This is not a short pathway, but we are going to be in phase one of clinical trials within about nine months and we think that will be very telling,” he said. “It will probably take about five years for us to get into the patient population because it takes a lot of rigor and testing to get there.”

Radspinner said the third thing the company is working on is an adjutant, which many companies are now considering because it reduces the amount of vaccine needed by a patient. “It also enhances the effectiveness,” he said. “If we added it to our vaccine and our device, in an ideal world, you could see (efficacy) rates getting even better. We’re doing a lot of work on that so we can get it rapidly into the clinic. We want to push that forward.”