



\* Mouse will not actually be expected to swallow a pill. That would just be crazy.

COVER STORY

## IF YOU GIVE A MOUSE A VACCINE ...

*Memphis-based US Biologic is ready to take a vaccine to market that could help the fight against Lyme disease and open up exciting new ways to prevent infectious illnesses. But it all begins with this little guy.*

JOHN KLYCE, PAGES 6-10



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# MEET HANK. HE'S A BIG PROBLEM. A MEMPHIS FIRM MAY HAVE THE SOLUTION.

## LET'S BEGIN WITH A BLACKLEGGED TICK. AT THE RISK OF ANTHROPOMORPHIZING, WE'LL CALL HIM HANK.

A fledgling tick, Hank is a larva, and to move into the next stage of his life cycle, a nymph, he needs a meal – specifically, a blood meal. So, young Hank, ever determined, latches on to a white-footed mouse – we'll call her Lisa – and begins to feed. But there's a problem. Lisa is infected with the bacteria that causes Lyme disease; and now, it's spread to an unwitting Hank. He's become a vector.

If Lisa's blood was his last meal, this might not be a problem. But Hank's story isn't finished. He transforms into a nymph and needs another blood meal to reach his next life stage, that of an adult male tick. As it happens, strolling through the woods where he resides is a member of a species just loaded with blood: a human. We'll call him Jerry.

It should be noted that Jerry isn't an ideal host for Hank. He'd much prefer a wild animal coated in fur to a bare-skinned homo sapien who lives in a house and takes showers. But Hank can't see that Jerry is a human; he, like other ticks, can barely see at all. He selects a host by sensing their body heat and odors, and he latches on to Jerry.

If Jerry were to remove Hank quickly – say, in the first 24 hours – his chances of contracting the illness would be significantly reduced. But because Hank is a nymph, he's only the size of a poppy seed. Jerry doesn't even notice him.

And ultimately, he contracts Lyme disease.

Though this scenario is hypothetical, millions of similar, real-life stories have played out over the years.

US Biologic is ready to take a leap forward in the fight against Lyme disease. And that might only be the first step.

According to the Centers for Disease Control and Prevention (CDC) around 476,000 people are diagnosed and treated for Lyme disease annually, with typical symptoms including fever, headaches, fatigue, and a skin rash called erythema migrans. Even after being treated with antibiotics, issues like fatigue, pain, and joint and muscle aches can persist in some patients. And if left untreated, the illness can spread to joints, the heart, and the nervous system, which causes more severe symptoms that can be debilitating – like arthritis, facial palsy, heart palpitations, nerve pain, and inflammation of the brain and spinal cord.

It isn't a mystery as to how people contract the illness either. The CDC has said that people are infected with Lyme disease by blacklegged ticks, which can catch it by feeding on rodents. And in 2017, The Washington Post ran a story titled "Why this adorable mouse is to blame for the spread of Lyme disease," explaining that white-footed mice are primary carriers of the Lyme bacterium *Borrelia burgdorferi* – and a common host for blacklegged ticks.

Initially, Chris Przybyszewski, president of Memphis-based biotech company US Biologic, wasn't aware of the role played by ticks and mice. But as he learned more about Lyme disease and spoke to people afflicted by it, he came to realize the breadth of the issue.

"As I learned this and the impact of it, [I realized] it is a stunning health care problem in America," he said.

The number of mice carrying the Lyme disease bacteria, however, could be drastically reduced.

That's because this year, US Biologic is set to release a vaccine that will help the mice generate antibodies protecting against the bacteria.

## COVER STORY

BY  
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### If you give a mouse a vaccine ...

After forming its original team in 2011, incorporating in Tennessee in 2012, and taking years to research, develop, and test its product, US Biologic is slated to take its Lyme vaccine for mice to market in 2023, pending a greenlight from the U.S. Department of Agriculture (USDA).

The company is set to start by distributing its *Borrelia burgdorferi* Bacterin vaccine in the 16 states with the highest incidences of Lyme disease infection: Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia (including D.C.), West Virginia, and Wisconsin.

After this, the company plans to expand to meet market demand. But its efforts raise a question.

How exactly can you vaccinate mice on a mass scale?

Convincing people to get vaccinated can be difficult as it is; so how do you vaccinate a tiny creature that will dash away at the sight or sound of you?

So, US Biologic has come up with an alternative to the traditional form of vaccination. Rather than injecting the bacterin into a mouse's body, it's given to them orally, through pellets coated with the vaccine.

"Oral [administration] became the most logical thing," said Jolieke G. van Oosterwijk, Ph.D., US Biologic's chief scientific officer. "Because voluntary consumption is much easier than running after mice."

### 20,000 pellets in two minutes

Here's how it works. The company has a partnership with Purina, which provides it with brown, non-nutritive pellets that are the size of an acorn – the white-foot-

ed mouse's meal of choice – and resemble dog food.

These are shipped to US Biologic's 5,000-square-foot facility, located at Agricenter International, which was a former pellet-processing mill that the company has poured about \$500,000 into and retooled for its needs.

Here, it has a state-of-the-art coating machine provided by Missouri-based Spray Dynamics. Though known for coating snack foods with various flavors, the company has tailored this device for US Biologic.

The machine coats doses of the vaccine for two minutes. The pellets then go to a large, adjacent dryer – a machine once used to coat and dry almonds in Iowa – and dried for eight minutes. In a continuous process, US Biologic can produce 10,000 coated pellets a minute, and about 2 million in a day.

These pellets, ready to go, are then set to be brought to three markets. One, the residential market, focuses on homeowners. The others are the commercial market – think golf courses, colleges, sports facilities, and summer camps – and the public market, which focuses on places like federal parks, state parks, and military installations.

### 'Another arrow in our quiver'

All of this begs another question: How do you ensure the pellets get to the mice?

The pellets are set to be placed in the field by pest management professionals and located within US Biologic's LymeShield Stations – green and blue devices that have timed-release systems and are made from the same materials as football



**"We have to go faster. We can't wait until a million people are infected."**

**CHRIS PRZYBYSZEWSKI**,  
President,  
US Biologic

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helmets and garbage cans.

In the residential market, for example, a pest management professional would place the LymeShield Station on a paver stone and put it in a covered area in the yard. The station has openings that are the right size for a mouse – but not other animals – to crawl into, and within it are six wells that each have about 100 pellets. Every two weeks, a different well opens up and releases its pellets. And every three months, when all the pellets have been released and the station is empty, the pest control technician would return and refill it.

“We built this with three things in mind,” Przybyszewski said. “The first was safety. The second was making sure the dosing was correct, based on all the laboratory work. And the third was the pest management professional service delivery schedule. We wanted to make sure that we were mimicking when they would go out already for their normal services.”

Making the process convenient for pest management professionals was key, as they play a major role in the business plan for the vaccine. In the commercial and public markets, the company plans to contract with pest management professionals to apply the product.

And in the residential market, US Biologic intends to sell the product directly to pest management companies, which will in turn sell it to their customers.

Already, it’s in discussions with a variety of these companies.

“They will go to their customer base [of existing pest control customers] and say, ‘We have another arrow in our quiver that we can bring to your living environment,’” explained Steve Good, US Biologic’s chief commercial officer and a former Terminix executive.

Whether this arrow will be popular, though, remains to be seen. It is a new vaccine that comes with a new process, and Przybyszewski acknowledged that they “have not proven that people will buy it.”

“We have an enormous amount of market data, years and years of

**1. US Biologic research technician Argerie Marin discusses One Health, which addresses health problems by combining animal, human, and ecological dimensions.**

**2. US Biologic chief scientific officer Jolieke G. van Oosterwijk, Ph.D., and director of data and analytics John Brooke, Ph.D., discuss a new antigen created via the OrisBio platform.**

**3. US Biologic laboratory director and senior scientist Dr. Luciana Richer and process engineer Ian Johnson work in the lab with a tangential flow filtration device.**

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**US BIOLOGIC RECENTERED**

US Biologic plans to build a new facility at the Agricenter that would combine its HQ, R&D, vaccine production, and coating all at one location.



A2H

conversations with customers,” he said. “We understand there’s a pent-up demand. All that is true, without a doubt. But until money starts exchanging hands, you just don’t know.”

Still, Przybyszewski and co. are confident in the vaccine’s prospects and believe they “will have to work to keep up with demand.” And if all goes according to plan, the Lyme vaccine will just be US Biologic’s debut.

**‘The secret sauce’**

Right now, US Biologic has its HQ at 3 N. Dunlap St. – where it shares a building with the University of Tennessee Health Science Center police – and the facility at the Agricenter.

But its ambitions span far beyond this, as US Biologic plans to build a major campus at the Agricenter that would consolidate its headquarters, research and development, vaccine production, and coating all in one location.

Currently, the cost for such a facility is set at \$100 million – though this number could rise – and the first stage is set to encompass up to 80,000 square feet. The goal is to break ground in 2024 to keep up with anticipated product demand.

“The secret sauce in the middle is what we’re going to be doing at the Agricenter,” said Mason Kauffman, US Biologic’s CEO and board chairman. “We’re bringing it all together.”

This “secret sauce” could also benefit the Agricenter itself. To John Butler – president of the Agricenter, the research and education organization located in Shelby Farms Park – US Biologic’s goals align with its quest to make Memphis the agriculture technology capital of the world.

“Agriculture is changing significantly, and how food and fiber and the ag sector is perceived is changing,” Butler said. “So new, innovative ways to deliver vaccines is just a natural extension of that work. ... And the work they’re doing certainly represents the innovative component of the industry moving forward.”

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**'We can't wait'**

The work US Biologic is doing isn't confined to the Lyme vaccine either.

As it developed the vaccine for mice, the company's leaders learned how they could develop a more widely taken flu vaccine for people.

The Lyme vaccine couldn't be injected with a needle and couldn't have specific, high-maintenance temperature requirements. It had to be administered orally and voluntarily.

"When you think about all these things, it's exactly the same thing as the problem with vaccines in humans, right?" van Oosterwijk said. "They're hard to get. They're hard to store. They're not stable for a very long time. People don't like getting a needle. ... So, we started thinking, 'We have to go for the flu shot every year. What is something that everybody likes to eat?'"

The answer: A gummy.

US Biologic is developing a chewable flu vaccine in the form of a gummy that can be flavored, shaped into things like hearts and dinosaurs, and stored at room temperature. Though these could first be given by physicians, the ultimate goal is to have them shipped to people's doorstep.

The gummy is in a pre-clinical phase of testing; the goal is to begin human trials by the end of 2024.

Both the gummy and Lyme vaccine are also part of a bigger picture US Biologic is painting – a plug-and-play platform that its leaders believe could rapidly develop vaccines needed to prevent diseases from spreading in communities.

"We have to go faster. We can't wait until a million people are infected before we get them a vaccine or even a diagnostic for that matter. So, this is the technology that we can do," Przybyszewski said. "We can identify it, we can create the vaccine, manufacture at scale, get it regulated, and get it out to the populations that need it, either animal or human."

Take the chewable flu vaccine as an example. To combat bird flu, its oral delivery platform could remain the same, but it could be modified and given to birds in powdered form.



HEAT AND CONTROL

*US Biologic chief regulatory officer and chief manufacturing officer, Steve Zatechka, Ph.D., examines vaccine application equipment at the Agricenter.*

In that same vein, it could be adjusted for pigs to combat swine flu and given to them in a hard, grain-like substance.

The vaccine can also be adjusted to more effectively fight different variants of the flu.

"We can adjust that antigen very rapidly, because everything is the same except for that one piece that we can switch out," van Oosterwijk said. "That's the plug-and-play aspect of the platform: 'What animal are we going to do? What do they eat, and how do they eat? Then, also, what is the disease?' All these particular aspects can be changed."

The US Biologic team maintains, though, that it won't be sacrificing safety for speed. The entire

platform, Przybyszewski said, has been "de-risked, and there are very, very few unknowns." Rigorous testing will be required for all the vaccines, he added, and there will be "no shortcuts on safety at any point."

The products will also still have to gain regulatory approval. And for a new vaccine, that process can be long and arduous.

"If this is the first product – we've never seen the antigen, we've never seen the platform that has been used on them, and we've never seen it used in such a way – it can take anywhere from 10 to 20 years to get that through regulatory," van Oosterwijk said.

But as a company moves on to its next products, regulatory agencies like the U.S. Food and Drug Admin-

istration and USDA will come to understand how it's creating them. They'll inspect its facilities on a regular basis and know exactly what the company is doing. And approval for the other products can come much more quickly.

"We tell them, 'I go to work every day; I take a right on Poplar, go five miles, and take the left on Poplar.' And they say, 'OK, you can go to work like that. That will be approved.' That is our vaccine, including the platform," van Oosterwijk said. "Then when I say 'I want to go to the gas station halfway,' all I need to do is tell them I am doing that and have them inspect the gas station. And then I can continue. So these other parts stay exactly the same." ❧