Hate needles? Flu vaccines of the future could be skin patches delivered to your door.

Vaxess, a Cambridge startup with ties to Harvard, MIT, and Tufts, raised \$27 million to test its technology in clinical trials after developing the idea for more than a decade.

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Cambridge startup Vaxess created a "microneedle skin patch" as an alternative to a traditional flu shot. The company raised \$25 million to test its technology in clinical trials after developing the idea for more than a decade. JESSICA RINALDI/GLOBE STAFF

Hate needles? Flu vaccines of the future could be skin patches delivered to your door. - The Boston Globe in the inture, getting a nu shot might be as easy as opening the manbox and slapping a

skin patch on your arm.

Immunizations shipped to doorsteps around the globe is the dream of Michael Schrader, chief executive and cofounder of Vaxess. For more than a decade, the Cambridge startup - whose name is a portmanteau of "vaccine" and "access" - has inched toward the creation of a vaccine that's easy to use, doesn't require refrigeration, and releases slowly in the skin for a stronger immune response.

On Wednesday, Vaxess announced that it raised \$27 million in series B funding led by the Boston biotech investor RA Capital Management. The money helped the company finally begin the first clinical trial of its technology in August. Results from the 45-person study of a flu vaccine patch are expected by the end of the year.

It's a pivotal moment for the nearly 11-year-old startup, which was founded by Harvard Business School students and based on science from Tufts University and MIT. If the trial goes well, Vaxess could gain an additional \$10 million from its current investors and will begin seeking more funds for bigger tests of its technology.

Success would also bode well for other startups and academic labs developing their own skin patch vaccines. These experimental vaccines replace one large needle with dozens of teeny tiny ones. Those microneedles are just long enough to slip the vaccine under the skin's surface, but are too short to prick nerves.

"Conceptually, the idea is straightforward. You have a patch with some little things poking out and you stick it on your skin," said Mark Prausnitz, a chemical and biomolecular engineer at Georgia Tech, and the chief scientific officer and cofounder of microneedle vaccine startup Micron Biomedical.



Vaxess chief executive Michael Schrader inside the lab where the Cambridge biotech startup is developing microneedle skin patch vaccines as alternatives to traditional flu shots. JESSICA RINALDI/GLOBE STAFF

But scientists have been working on microneedle patch vaccines for more than two decades. Only a few of them have made it into early clinical trials. None have been approved. And venture capital firms and large pharma companies have been hesitant to invest in the approach.

Yet challenges in globally distributing the COVID-19 vaccines, which have to be stored in refrigerators or freezers, highlight the need for new approaches, said Dr. Mark Poznansky, director of the Vaccine and Immunotherapy Center at Massachusetts General Hospital. "The pandemic made microneedle vaccines relevant again," he said.

"Now there needs to be a breakthrough study in humans that really demonstrates that it works," he added.

Vaxess was founded by four Harvard Business School classmates who became interested in a method using silk proteins to stabilize vaccines. Schrader hoped that the trick, developed by Tufts scientists Fiorenzo Omenetto and David Kaplan, could be used to make vaccines that don't require cold storage.

"Vaccine developers were intrigued by the technology, but they couldn't figure out how they were going to make more money with it," Schrader said.

In 2014, Schrader saw a paper from MIT scientists Darrell Irvine and Paula Hammond that paired the stabilizing properties of silk with a microneedle patch to make a vaccine that released slowly in the skin over a couple of weeks to spur stronger immune responses. "It was a perfect extension of our work," Schrader said.



Kate Skrada, a senior research associate in immunology at Vaxess, worked to develop a test that will look for a range of immune responses from blood samples in the company's ongoing clinical trials. JESSICA RINALDI/GLOBE STAFF

Vaxess switched gears to develop its own microneedle patch, initially working with the MIT team through a grant from the Bill & Melinda Gates Foundation for a few years. It wasn't easy.

"You almost would have to be naïve to try and do what we're doing," Schrader said. Keeping the vaccine stable, filling microneedles evenly, and getting them to release the vaccine slowly are each "incredibly complex" problems, he said. Combining them is harder still.

The resulting patch is about an inch wide, with an array of 121 clear microneedles, each just a fraction of a millimeter long and made from a mixture of silk, sugar, and other polymers. A small spring-loaded device ensures that people stick the patch on skin correctly.

"You feel a mild slapping sensation, like a rubber band, but you don't actually feel the needles themselves," Schrader said. "You only wear the patch for five minutes and take it off. But the vaccine stays behind in your skin and slowly releases over two weeks."

Until recently, the company has largely relied on grants from the Gates Foundation and government agencies to fund its work. It's been especially hard to raise money from venture capital firms, which often eschew vaccine startups in favor of biotech firms working on more lucrative medicines for cancer or rare diseases. "We were told many times along the way that we should forget vaccines and go focus on low volume, high margin products," Schrader said.

"COVID has changed this dramatically," Schrader added, since vaccines for the disease were not only important, but highly profitable. "We have gotten inbound calls from venture funds that five years ago would not touch vaccines, and they are now interested," he said.



A view of the Cambridge biotech startup's skin patch and its 121 microneedles that are designed to deliver a flu vaccine just under the surface of the skin. JESSICA RINALDI/GLOBE STAFF

Mario Barro, a director of innovation at RA Capital, said in an e-mail that the pandemic "inspired" the firm "to make vaccine innovation an explicit part of its investment strategy." Vaxess stood out to the firm for its "unique approach" to eliminating the need for cold storage, and for the potential ease of delivery, he added.

MIT's The Engine, Mission BioCapital, and the Global Health Investment Corporation also contributed to Vaxess's new funds. Ann DeWitt, general partner at The Engine, hopes the startup's flu study is just the first of many to come. "It lays the groundwork for the next set of vaccines and medicines that can go into this platform," she said.

Vaxess must first prove that its microneedle patches are at least as safe and effective as

Hate needles? Flu vaccines of the future could be skin patches delivered to your door. - The Boston Globe existing flu shots. A study in mice suggests the patches are better at protecting mice from the flu. But Posnansky cautioned that keeping the vaccine in the skin for two weeks

might also trigger more unwanted reactions to the vaccine, such as swelling, pain, or fever. "There's sort of a ying and a yang to that," he said.

Even if the patches work, Vaxess will face the hurdle of figuring out how to make them in large quantities and at affordable prices. The startup's manufacturing facility in Woburn can only make 1,000 patches a week by precisely injecting drops of the silk and vaccine mixture into tiny holes in the mold. "Fine-tuning that was a major challenge," Schrader said.

Vaxess ultimately hopes to produce 100 million patches a year. Schrader said that the Biomedical Advanced Research and Development Authority, part of the US Department of Health and Human Services, has already paid for the design of a facility of that scale. But turning those blueprints into a building could cost hundreds of millions of dollars, he added. "I'm acutely aware of how big of a bottleneck this is going to be for us."

Omenetto, one of the Tufts engineers behind the silk technology and an adviser to Vaxess, is hoping the startup's clinical trial is a long-awaited turning point for the company. "They took a very, very difficult project and made it into something that is poised to become reality," he said. "It makes me feel really good about where the technology is going."

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