

This Company Boasted to Trump About Its Covid-19 Vaccine. Experts Are Skeptical.

Inovio, a Pennsylvania biotech company, has spent years claiming to be on the cusp of important vaccines. It has never brought one to market.

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As the deadly new virus spread globally, Inovio Pharmaceuticals, a small biotech company in Pennsylvania, rushed to develop a vaccine. After announcing promising early results, Inovio's stock soared more than 1,000 percent. Riding the momentum, the company sold more shares to the public.

That was 2009, when H1N1, better known as swine flu, was stoking fears of a devastating pandemic. In the years since, Inovio has announced encouraging news about its work on vaccines for malaria, the Zika virus and even a "cancer vaccine." The upbeat declarations have caused the company's stock price to leap, enriching investors and senior executives.

There's only one catch: Inovio has never actually brought a vaccine to market.

Now, with a new pandemic raging, Inovio is working on a new vaccine: for the novel coronavirus. A flurry of positive news releases about its funding and preliminary results have sent Inovio's shares up by as much as 963 percent — and helped the company attract money from the government and investors. At the same time, Inovio insiders have sold stock.

But some scientists and financial analysts question the viability of Inovio's technology. While there are some early signs of promise with the company's vaccine, Inovio has only released bare-bones data from the first phase of clinical trials. It is locked in a legal battle with a key manufacturing partner that claims Inovio stole its technology.

Shareholders have sued Inovio, claiming it has exaggerated its progress on a coronavirus vaccine to inflate its stock price. Adding to the challenges, Inovio's potential vaccine will have to be administered by a gadget — it resembles an electric nose-hair trimmer and is called the Collectra — that would direct genetic material into millions of patients.

And while the company has said that it is part of Operation Warp Speed — the flagship federal effort to quickly produce treatments and vaccines for the coronavirus — Inovio is not on the list of companies selected to receive financial support to mass-produce vaccines.

"The absence of that funding, coupled with their ongoing litigation, coupled with the need to scale a device, coupled with the absence of complete Phase 1 data, makes people skeptical," said Stephen Willey, an analyst at Stifel, an investment firm.

As it tries to defuse the coronavirus crisis, the Trump administration is wagering, in part, on companies — like Moderna and Novavax — with spotty track records and penchants for self-promotion. In June, Inovio received \$71 million from the Department of Defense to manufacture its battery-operated Collectras.

Some medical experts worry that taxpayer backing for unproven companies could erode the public's already tenuous faith in vaccines.



Inovio's Research and Development Center in San Diego, Calif. The company's specialty is attempting to develop vaccines that use a virus's own genes to provoke an immune response. John Francis Peters for The New York Times

“If you dry up trust, you’ll have almost a self-defeating proposition with vaccine uptake,” said Arthur L. Caplan, a bioethicist at the New York University School of Medicine. “The more you’re hype and less you’re reality, the more you are taking funds away from things that are cheaper, closer or both,” he added.

Inovio could provide an update on its progress with the vaccine when it releases its second-quarter financial results on Monday.

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Developing vaccines is hard. In addition to coming up with an effective formula and the funding to produce it, drug makers need to navigate an obstacle course of government safety checks and rigorous scientific review on a fast enough timeline to stay competitive. The fact that a company like Inovio has never brought a vaccine to market is not necessarily an indictment of its underlying approach to creating vaccines. Otherwise, scientists say, the world would never have technological breakthroughs.

Inovio's specialty is attempting to develop DNA-based vaccines, which use a virus's own genes to provoke an immune response. But the company's decade of attempts have not borne fruit.

In fact, no DNA-based vaccine has ever made it to market. While some have produced encouraging results in small animals, they have not proven effective in humans — against the coronavirus or any other disease.

Nonetheless, the scientific community continues to believe the technology is promising in part because such gene-based vaccines can be designed quickly. Companies in Korea, India and Japan are pursuing similar DNA-based coronavirus vaccines.

Inovio's chief executive, J. Joseph Kim, has said that when the DNA sequence of the coronavirus became public in January, the company was able to immediately engineer a vaccine. Later that month, Inovio secured a \$9 million grant from the Coalition of Epidemic Preparedness Innovations, a leading funder of vaccine research.

In March, Dr. Kim — an immunologist who became chief executive of Inovio in 2009 — was invited to participate in a meeting in the White House's Cabinet Room with President Trump and pharmaceutical executives.



President Trump held a meeting in March with pharmaceutical executives, including Inovio's Dr. Kim. Drew Angerer/Getty Images

At the public meeting, Dr. Kim described Inovio as “the leader in coronavirus vaccine development in the world,” adding that it had its own manufacturing capabilities.

Mr. Kim said that, thanks to “our very innovative, 21st-century platform,” Inovio had been “able to fully construct our vaccine within three hours.” All the company needed now, he told Mr. Trump, was the federal government’s support to help scale up manufacturing.

Inovio’s stock shot up 220 percent over the coming days. Its market value has gone from less than \$500 million at the start of the year to more than \$3 billion today.

Shortly after the White House meeting, Inovio announced that it had received a \$5 million grant from the Bill and Melinda Gates Foundation. The money would help Inovio test the Collectra. The devices use electrical pulses to direct DNA into patients’ cells — a technique that experts said is grounded in legitimate science.



Inovio's Collectra gadget for directing genetic material into patients' cells. Inovio

Some investors, though, had grown skeptical.

On March 9, Andrew Left of Citron Capital, which is shorting Inovio's stock and stands to profit if it declines, began publicly questioning Inovio's approach to devising a coronavirus vaccine and accusing it of engaging in "serial stock promotion." He later issued a report comparing the company to Theranos, the disgraced blood-testing company, and cataloging Inovio's history of promoting and then failing to produce vaccines.

Inovio's stock price plunged 66 percent, though it would soon soar to new heights thanks to optimism about its potential vaccine.

Days later, shareholders sued Inovio in federal court in Pennsylvania. Citing Dr. Kim's remarks at the White House and earlier comments he made on Fox Business Network about having created a vaccine, the suit claimed that the company had "capitalized on widespread Covid-19 fears by falsely claiming that Inovio had developed a vaccine." In April, another group of shareholders filed a separate suit in the same court, accusing Dr. Kim and Inovio's board of mismanagement and unjustly enriching themselves, among other things.

Inovio has disputed Mr. Left's critiques, but the company publicly clarified that it had developed a vaccine construct — essentially a road map — not an actual vaccine. Inovio has not publicly responded to the pending shareholder lawsuits.

Over the past 10 years, insiders at Inovio have sold more than \$25 million in stock, according to the financial data provider Equilar. Last year, Dr. Kim was forced to sell about half his Inovio shares — causing the stock price to drop by more than a third — after he used his shares as collateral to borrow money and was caught in a so-called margin call, requiring him to immediately repay his loan.

This year, following steep run-ups in Inovio's stock price, insiders have sold \$3.8 million in shares. (Earlier this year, Inovio banned executives from "engaging in short-term or speculative transactions in the company's securities, including pledging and purchasing company securities on margin.")

Hoping to raise money to fund its vaccine efforts, Inovio said this year that it planned to sell some \$150 million in new stock to investors.