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# Little Fed support for firm’s ‘better’ vaccine

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It’s working with a company facing intense scrutiny from American politicians and regulators, but a Canadian pharmaceutical start-up says the COVID-19 vaccine the firms are making together might be better than anything on the market.

The real problem for Providence Therapeutics, says CEO Brad Sorenson, is lack of interest from Ottawa.

The Alberta company’s messenger-RNA shot could be rolling out of the Emergent Biosolutions plant in Winnipeg before year’s end, Sorenson said last week, shortly after Emergent executives underwent a public grilling by U.S.lawmakers.

The Maryland-based manufacturer has taken heat in Congress and the U.S.media for ruining 15 million doses of Johnson & Johnson vaccine, struggling with quality-control problems at its Baltimore plant and generating spotty results from a lucrative government contract.

The firm’s little-known Winnipeg facility, not implicated in the U.S.controversy, is slated to do the final stages of manufacturing on the Canadian vaccine.

That collaboration has been “great,” said Sorenson, whose firm made headlines earlier this year when Manitoba

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Brad Stevens, left, and Brad Sorenson of Providence Therapeutics, photographed here at Northern RNA in Calgary on Jan. 25, say the COVID-19 vaccine they’re developing may be better than the Pfizer and Moderna vaccines.

purchased two million doses of its product in advance, independent from the federal vaccine-procurement program.

But plans are up in the air as Ottawa has shown scant interest in pre-ordering any of the Providence vaccine itself, despite encouraging early results, he complained.

Meanwhile, the government announced it is funding a new plant that will make the same kind of mRNA vaccine — once the factory is complete in three years.

“Canada just gave \$200 million to a company with no experience in messenger-RNA to build an mRNA facility in Ontario,” said Sorenson. “Why invest in something that will produce vaccines in 2024 when we ... can produce this year?” “So far, the Canadian government hasn’t shown an inclination to talk to us about purchasing Canadian.”

Results from Providence’s recently completed Phase-1 trial — which have

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yet to be submitted to a peer-reviewed journal — indicate it generates an immune response even better than leading vaccines made with the same technology by Pfizer and Moderna, he said.

Without a major Canadian purchaser of the vaccine, though, it might be forced to relocate manufacturing to a country like India or China with much lower costs, said Sorenson.

In fact, the government does recognize the potential of the Providence vaccine, said John Power, a spokesman for Innovation, Science and Industry Minister François-Philippe Champagne. It's already provided \$10 million in financing and committed to support it through a Phase-2 trial, he said.

Champagne spoke directly to Sorenson and the company's board chair "to discuss our continued support for their work," said Power.

But he didn't say whether the government would actually procure any of the vaccine and warned that if Providence moved operations outside of Canada, that "could jeopardize their access to ongoing financial support."

The federal government has ordered in advance vaccine from seven other manufacturers. If all is delivered, it would be enough to fully vaccinate every Canadian several times over. Booster shots may be needed in future.

Emergent, having received a contract from the U.S. government worth \$628 million, was making vaccine in Baltimore for both Johnson & Johnson and AstraZeneca. A batch of the J&J product was contaminated with an ingredient from the other, forcing it to be scrapped.

Then a U.S. Food and Drug Administration report divulged a litany of problems still apparent after that incident, saying conditions at the facility could lead to further contamination.

As first reported by Postmedia News, most of the AstraZeneca vaccine shipped to Canada by late April was made at Emergent's Maryland plant, though American authorities have not allowed any of it on to the U.S. market.

An investigation by the U.S. House of Representatives sub-committee on the coronavirus crisis has raised concerns as well about the government contract, personal stock sales by top executives and bonuses paid to them — all before any of the COVID vaccine has made it into American arms.

The company's plant in Winnipeg was part of its 2013 purchase of Cangene Corp., a specialty pharmaceutical and contract manufacturer.

The Providence mRNA vaccine employs the same groundbreaking new technology as the Moderna and Pfizer shots. That essentially involves injecting a piece of genetic material that activates the immune system to fight off the COVID virus.

The mRNA ingredient is being made by Calgary's Northern DNA and a U.S. company. Emergent Winnipeg will combine the solution with lipid particles that form a sort of coating around it, and do the "fill and finish" — putting the resulting serum into vials for shipment, said Sorenson.

After promising Phase 1 results, Providence is in talks with various developing countries — many of whom have obtained little or no vaccine so far —

and with the World Health Organization about joining a WHO-run Phase-3 trial, he said.

Sorenson said he couldn't provide detailed data from the first trial as the results are being prepared for submission to a peer-reviewed journal by researchers at Toronto's Sunnybrook Research Institute and the University of Toronto.

He argued the Providence shot is the mRNA vaccine furthest along the pipeline after Pfizer, Moderna and German company CureVac, whose product is on the verge of being approved in Europe.

But one expert following vaccine developments closely said he will be skeptical until seeing more evidence.

"Considering that no established pharmaceutical company in the high-tech hot spots of the world — San Francisco, Boston, London, Frankfurt, Tokyo, Seoul, Shanghai, etc. — has pulled off a copycat mRNA vaccine, what's the likelihood that an unsung company from Calgary using a troubled partner's Winnipeg factory could?" asked Amir Ataran, a health policy and law professor at the University of Ottawa with a doctorate in immunology.

Underlying the Providence story is controversy over lack of vaccine-production capability in Canada — considered a key factor in the slow delivery of COVID shots here. Federal officials have said none of the vaccines that made it to the market first could be manufactured in this country.

But Matt Hartwig, a spokesman for Emergent, said the company has discussed proposals with Ottawa for man-

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ufacturing vaccine under contract at its Winnipeg plant. The facility can turn out a million multi-dose vials a month, with the potential to expand, he said.