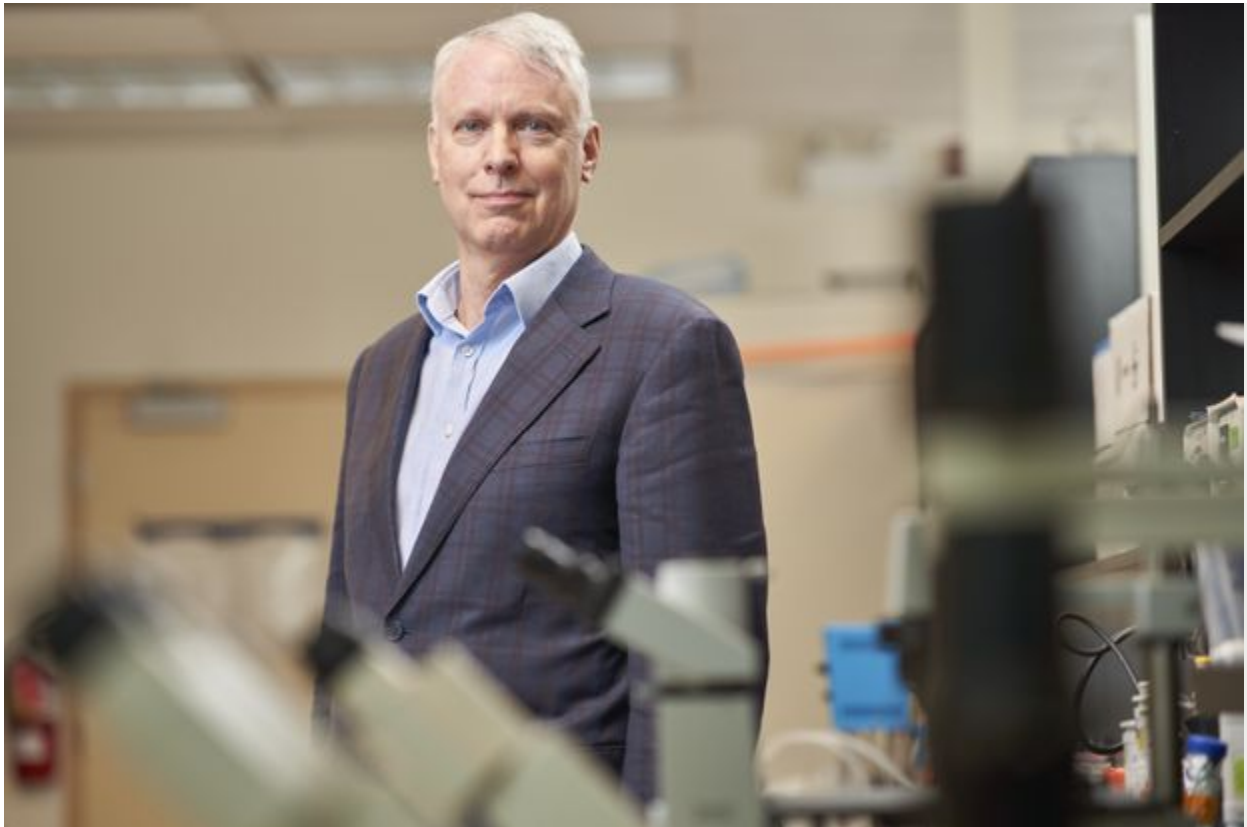


Investors flock to Canadian device maker Sernova hoping to transform how diabetes is treated

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Sernova President and CEO Dr. Philip Toleikis poses for a photo in the company's lab in London, Ontario on Jan. 19, 2021.

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A tiny London, Ont., medical device company hoping to change how diabetes is treated has had a wild ride of late. Last Friday, stock in Sernova Corp.

SVA-X +0.61%increase

shot up 65 per cent on the TSX Venture Exchange, then nearly doubled on Monday, closing at \$2.42 a share. At its peak, Sernova had a market capitalization of \$630-million, making it one of Canada's 15 most valuable publicly traded life sciences companies.

But then the stock, which is primarily owned and traded by non-institutional investors, lost 32 per cent of its value over the next three days. Even so, at Thursday's \$1.64 closing price, Sernova is still well above the range of 10 cents to 30 cents it has traded in for most of the past decade.

The sudden interest in a 10-person company that has toiled in near anonymity for years on the campus of Western University is owing to two factors. Last Friday, Sernova released some promising, albeit limited and preliminary, clinical data.

"It's nice to see Canadian progress in an area where we're always quite proud – insulin and diabetes," said Michael May, chief executive of the Centre for Commercialization of Regenerative Medicine. "But ... a lot more clinical trials and experiments will have to be done."

Sernova stock has also benefited from the successful initial public offering last month of cell therapy developer Sigilon Therapeutics, which works in similar therapeutic areas, followed by Sana Therapeutics, which filed to go public last week – both offerings at much higher valuations than Sernova. Investors "realize our stock is undervalued," Sernova CEO Philip Toleikis said in an interview.

All three companies are years from getting products to market and face significant hurdles. "This [Sernova] study is the first serve in the tennis match to determine whether we have an approvable device or not," said Doug Loe, an analyst with Leede Jones Gable, who this week upped his stock price target for Sernova to \$2.50 from \$1.

But that is also the nature of the biotech business. Stock spikes or plummets accompany key milestones in the costly, lengthy process to prove a product's safety, effectiveness and worthiness of regulatory approval. Fortunes can be won or lost by investors along the way.

Sernova has spent more than a decade developing an alternative method to deliver insulin for type 1 diabetes patients. The main standard of care since the discovery of insulin by Canadian researchers 100 years ago has been taking blood-sugar readings and injecting insulin daily.

Sernova's head office, on a road named after insulin co-discoverer James Collip, is seven kilometers from the "birthplace" of insulin: Frederick Banting's onetime home. Despite insulin's legacy, production is dominated by three non-Canadian giants: Eli Lilly & Co., Novo Nordisk A/S and Sanofi SA.

Researchers since the 1990s have transplanted donated insulin-producing cell groupings known as islets into diabetics with some success. In 2000, The New England Journal of Medicine reported that seven diabetic patients in a University of Alberta study who received transplanted islets were able to forego insulin injections for a year, although they had to take anti-rejection drugs with side effects. Given the limited number of islet donors, drug companies have turned to developing islets derived from stem cells.

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“We now know we can actually do that [with stem cells], so we have to figure out how to scale that up,” said David Prowten, CEO of the Juvenile Diabetes Research Foundation Canada, which has funded Sernova’s research.

Because the immune system attacks foreign objects, Sernova and several other device developers have focused on building implantable organ-like mechanisms to host and protect the cells.

Sernova’s device, called the “Cell Pouch,” is a business-card-sized implant inserted in a person’s lower abdomen. The polymer device is porous, so tissues fuse in and around it, forming an organic chamber and on-ramps to the bloodstream large enough to let in enough blood to gauge the body’s glucose levels, but small enough to keep out immune cells. Once tissues have wrapped around and inside the pouch, donated islets are transplanted into the chamber.

The hope is that the pouch can function for years without replacement or replenishment, Dr. Toleikis said. Sernova is also developing other uses to counter hemophilia and thyroid loss.

Sernova has generated data since the early 2010s, showing the device is safe in pigs and humans. But last Friday, principal clinical investigator Dr. Piotr Witkowski presented a key sliver of information from a continuing study, sanctioned by the U.S. Food and Drug Administration, of seven people with a severe form of diabetes to an American Society of Transplant Surgeons symposium.

Dr. Witkowski reported that two patients who had islet transplants had shown “defined clinical benefit with a clinically meaningful reduction in daily insulin injections,” including an absence of serious hypoglycemic events. Blood levels indicated insulin from the cell pouch was getting into the blood. One patient was able to go without an insulin shot for nine months, although that person also got another islet transplant into the liver similar to what U of A researchers have done for years.

“If they can reproduce this in other patients, this is an incredible result,” said Paradigm Capital analyst Scott McAuley.

But the small number of patients, the need for multiple infusions and the use of immunosuppressants in the study mean the early results “are a positive step, but it’s not exactly at the edge of a major breakthrough,” said Dr. Brey Paty, a clinical associate professor at University of British Columbia who used to work with the U of A group. “They’re showing in principle the pouch works, the cell survives and that they produce insulin. That’s promising and positive, but I don’t see it as earth-shattering.”

But Dr. Toleikis is buoyed. If the study is successful, he expects the FDA to green-light another, expanded study. Sernova has raised \$50-million to date and hopes to pursue a

Nasdaq listing. Dr. Toleikis believes regulatory approval could come by 2025 “if everything goes well and moves smoothly,” he said.

Sernova is also developing coating technology that could further protect transplanted islets from immune cells.

Meanwhile, Dr. Toleikis is working to fill a gap in Sernova’s treatment by securing a steady, scaleable source of islets. He admits Sernova is behind in efforts to develop its own stem cells, so he’s pursuing partnerships with pharmaceutical companies to provide the material.

“You get a licensing deal like we’re working really hard to get and, all of a sudden, the stock will start taking off again,” he said.

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