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Newco news

Servatus advances live microbial biotherapeutics after AU$7.5M capital raise

By Tamra Sami

PERTH, Australia – After raising AU$7.5 million (US$5.4 million) in a private placement, biopharma company Servatus Ltd. is advancing its microbial biotherapeutics clinical programs targeting serious autoimmune conditions. The Coolum, Queensland-based private company is focused on identifying and developing live microbial biotherapeutics and engineered proteins to treat chronic and autoimmune diseases, as well as non-antibiotic treatments for bacterial infections.

The funds raised will be directed toward clinical trials for insomnia, rheumatoid arthritis, and the chronic inflammatory bowel disease ulcerative colitis.

"While there are drugs on the market for insomnia and rheumatoid arthritis, a meaningful percentage of patients remain very much underserved by, or unable to tolerate existing therapies," Servatus CEO Wayne Finlayson said. "We had exceptional responses to our earlier work and are looking forward to moving into the clinic."

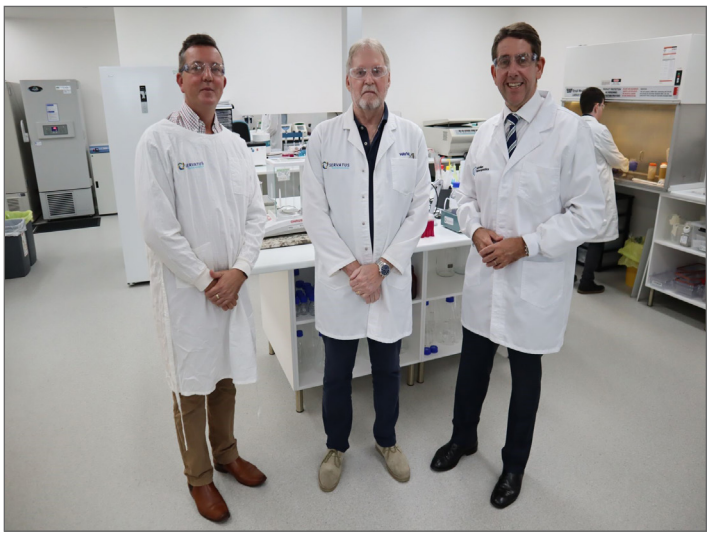
Finlayson and Wolf Hanisch co-founded Servatus in 2012. The two met in the U.S. in the 1980s when Finlayson was at the University of California, Berkeley as a post-doc research fellow. Hanisch died of cancer in 2019, and Servatus is part of his legacy, Finlayson said.

The genesis of the company centered on a protein that was discovered in Australia in the 1990s that had some immunomodulatory effects, "but it wasn't quite right, because it wouldn't last in the body long enough, and we had some stability issues," he said.

A protein engineer, Finlayson was able to re-engineer the protein to make it more stable and to have a longer serum half-life.

"At the same time, I had been interested in live biotherapeutics, and I brought some microbiome-based drugs into the company as well. Then we realized there was a scientific link as to what was going on with the human protein we were working on and why the bacteria were working.

"We have two aspects to the company, and the live microbials have taken over because they're an oral delivery and easier to produce and go through clinical trials.



(L-R) Robert Skelton, Labor MP; Wayne Finlayson, CEO, Servatus; Cameron Dick, treasurer for Queensland. Credit: Servatus Ltd.

"We work with a consortium of bacteria, and each combination is rationally designed to treat particular indications," he said.

Most drugs in the autoimmune space are not bacteria, and most companies working with bacteria are looking at inflammatory bowel disease and *Clostridioides difficile* (*C. diff*), and some are looking at cancer, he said but not many are looking at the autoimmune space, he said.

"We noticed when we did some early preclinical data that we were getting great results with combinations of our bacterial suite and on the drugs," he said, pointing to preclinical results in ulcerative colitis and rheumatoid arthritis, programs which are slated to enter the clinic in 2022.

"We chose *Helicobacter pylori* (*H. pylori*) because everyone else was choosing *C. diff*, and Australia has a bit of history with *Helicobacter pylori*."

Australian researchers Barry Marshall and Robin Warren discovered the bacterium *H. pylori* and deciphered its role in gastritis and peptic ulcer disease for which they received the Nobel Prize in Physiology or Medicine in 1982.

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Microbial biotherapeutics leading the way

Servatus' live microbial biotherapeutics (LMBs) are the most advanced therapies in its pipeline. SVT-1B149 is in a phase I trial in chronic idiopathic constipation and two phase I/II clinical trials are set to launch in Queensland for insomnia (SVT-4A1011) and rheumatoid arthritis (SVT-6A479), complementing existing trials in inflammatory bowel disease, *H. pylori* infection and chronic idiopathic constipation/irritable bowel syndrome with constipation.

The company has development programs that combine its LMBs with standard of care therapies, as well as an engineered protein for rheumatoid arthritis and psoriasis. The bacteria are derived from different combinations to treat different indications. Generally, there are three to five different combinations of bacteria in each drug.

In preclinical studies, Servatus' drug candidates were shown to either significantly improve the performance of leading autoimmune drugs or to outperform current standard of care drugs.

"We know the genetics of the bacteria and what we're looking for," Finlayson said, noting that he expects to have three indications in phase II trials in 2022.

The rheumatoid arthritis market is one of the largest drug markets globally, recording $43 billion in sales in 2018, while the insomnia market is expected to reach around $7.5 billion in 2026.

Servatus' business model consists of three integrated divisions: drug development, which is at the forefront of its microbiome based biotherapeutics; manufacturing via a joint venture called Australian Biotherapeutics with an unnamed multinational company; and an over-the-counter live microbial biotherapeutics business, called Biomiq.

The new research and production facility employs a state-of-the-art biomanufacturing process that pairs closed-system single-use continuous production with Australian-first drying technology to improve both manufacturing yields and production costs.

The joint venture will produce biopharma products for the export market, providing a revenue stream for the group.

To date, Servatus has raised roughly AU$15 million to $AU20 million, and it has about 22 employees. The company name is derived from St. Servatus, a fourth century patron saint associated with healing powers for a range of ailments, including rheumatism.

Servatus joined forces in 2021 with six international microbiome biopharma companies to form the Microbiome Therapeutics Innovation Group (MTIG), a coalition of companies devoted to progressing approved microbiome-based drugs. MTIG member companies include Seres Therapeutics Inc., Rebiotix Inc, Siolta Therapeutics Inc., Takeda Pharmaceutical Co. Ltd; Vedanta Biosciences Inc., and fellow Australian biotech Microba Ltd.

"It has been very satisfying to see the benefits of our integrated business platform this year," Finlayson said. "Our rapidly advancing clinical trial program has been supported by our state-of-the-art R&D and production facility. While other drug developers may have been impacted by short supply in manufacturing, having a purpose-built facility has enabled us to fast-track our clinical trial program. We are very proud to be able to take our Australian technology to the world and are entering into an exciting phase for the company."