Inaugural scholarship winner: disruptive innovation in healthcare

Dr Noelle Sunstrom, winner of the inaugural Women in Export Scholarship, is at the forefront of an emerging industry that is disrupting healthcare and putting effective treatments in the hands of more patients.

Many of the world's most powerful life-saving treatments are so expensive that people simply can't access them.

Known as biologics, these drugs are made using biological sources – that is, living things – and are far more effective than chemically synthesized drugs. However, because they are so complex, and take many years to progress through experimentation and clinical trials, they are prohibitively expensive when they reach the market. They typically sell for thousands of dollars per dose.

Sydney-based molecular biologist Dr Noelle Sunstrom is at the forefront of a relatively new industry that will put biologics in the hands of more patients globally. Through her biopharmaceutical company NeuClone, Sunstrom and her team are developing and commercialising high-quality biosimilars using proprietary technology developed in Australia.

A biosimilar is a highly identical copy of a biologic drug, but can sell for up to 30 per cent less. As some of the 'blockbuster' biologics begin to come off their patents, a new opportunity is emerging. It's a growing global industry that could save billions in healthcare costs.

Using groundbreaking technology that enhances the production of biologic drugs and reduces the cost of manufacture, NeuClone is making biosimilars to treat diseases such as cancer and autoimmune disorders. The company has partnered with Serum Institute of India, the world's largest vaccine maker, to manufacture these high-quality drugs on a large scale.

NeuClone and Serum will together advance each drug through Phase I clinical trials in Australia. After successful completion of Phase I, NeuClone will have sufficiently de-risked each drug to pursue a licensing deal with a suitable pharmaceutical partner. NeuClone is seeking one or more large pharmaceutical partners with broad geographic marketing reach to prosecute global Phase III trials and be NeuClone's route to market (the regulatory pathway for biosimilars does not require Phase II trials).

Through their technical innovations, Sunstrom and her team will give patients around the world access to life-saving drugs, including in countries where biologics have traditionally been inaccessible or unavailable.

The science of making a difference

In June 2017, in recognition of her innovative work, Sunstrom was announced the inaugural winner of the Women in Export Scholarship delivered in partnership by Austrade and Chief Executive Women (CEW).

The scholarship will take Sunstrom, CEW's newest scholar, to Boston, Massachusetts in July to attend Harvard Business School's 'Disruptive Innovation – Strategies for a Successful Enterprise' course.

"[The scholarship] is a wonderful opportunity to understand disruptive innovation," says Sunstrom. "That's exactly how we describe our company and partnership with the Serum Institute. We know that our processes are very disruptive. The combination of NeuClone's technology and Serum Institute's low-cost base manufacture means together we're going to drastically reduce the cost of these drugs worldwide."

Originally from Canada, Sunstrom obtained a PhD from McGill University in Montreal before moving to Australia on a post-doctoral scholarship with the John Curtin School of Medical Research at the Australian National University.

She began her academic research career at the University of New South Wales, where she led a team producing monoclonal antibody drug candidates and collaborating with large pharmaceutical companies to take those drugs to market. She and her team developed cutting-edge ways to produce complex biopharmaceuticals for commercial production.

In 2000, Sunstrom co-founded Acyte Biotech, which commercialises intellectual property from the mammalian cell research groups at the University of New South Wales and now at University of Queensland.

She completed an Executive MBA in 2007 and soon after founded NeuClone. Sunstrom is also a Fellow of the Australian Institute of Company Directors and the Royal Society of New South Wales.

For Sunstrom, NeuClone's partnership with Serum Institute presents an exciting opportunity to create a positive global impact following years of scientific research and development.

"With my background in research, I did a lot of work on methods of biologics production but did not see the results through to the end user," she says. "Now we're taking drugs from beginning to end, from the lab to the patient. We'll be

able to see 10 of our products going to patients, and see the benefits that the patients will receive. I'm especially proud to ensure that these drugs will be made affordable to those patients in under-developed countries."

Innovation in life-saving healthcare

NeuClone currently has 10 biosimilars in the pipeline, including a copycat version of the highly effective breast cancer drug Herceptin. That biosimilar will go through clinical trials in the last quarter of 2017 and then on to global trials for regulatory approval and licensure around the world. Sunstrom expects it to be on the market by 2020. From 2018 onward, NeuClone will have two drugs per year entering clinical trials.

By partnering with Serum Institute, NeuClone has created a business model that's unique in an industry where big pharmaceutical companies traditionally develop and market their own drugs. Serum Institute is currently completing construction of highly specialised and compliant facilities to manufacture NeuClone's drugs for global supply, including the US and Europe.

"We hand over [to Serum Institute] an engineered cell line that is producing, for instance, an antibody for breast cancer that has certified biosimilarity with the originator drug," says Sunstrom. "We hand over a vial of cells in 1 millilitre – Serum Institute then scales that up, growing these living organisms to 20,000 litres of product."

It's a disruptive business model at the forefront of a disruptive industry.

"I think it's taken pharma by surprise in that they had recently dismissed the threat of competition due to the complexities involved in making these types of drugs," says Sunstrom. "Now they're realising, and there is real concern that their profit and market share is going to decrease from biosimilar competition."

When she heads to Boston's Harvard Business School in July, Sunstrom will be exploring theories and real-world examples of disruptive innovation, and how she can use those to build a disruptive and sustainable business model.

"I'm looking forward to getting as much information and as much knowledge as I can, not only from the world-renowned facilitator but also from my peers. I will be coming back with my head full of knowledge and hopefully a lot of ideas that will help me in making a big global impact from here in Australia," says Sunstrom.