ADVERTISING FEATURE

Taking on disease through regenerative medicine

Positive promise of stem cell therapy

Regenerating every cell, tissue or organ in the body, curing genetic disorders and chronic diseases, alleviating pain and delaying the onset of ageing, these are the altruistic promises of stem cell therapy.

A key driver of the regenerative medicine market, stem cell therapy's infinite applications have biotechs racing to the clinical trial finishing line.

More than 600 stem cell patents have been filed within Australia in the last five years and over 500 companies globally are involved in stem cell product development.

Oncology, cardiology and neurology remain the crucial areas of spend, but with the global pain market estimated to be worth $US69 billion and forecast to reach $US79 billion by 2024, Australian biotech Regeneus, a player in osteoarthritic and neuropathic pain, is in a prime position.

Regeneus' unique mesenchymal stem cell (MSC) platform comprises a combination of stem cells and secretions offering a more powerful therapeutic effect than stem cells alone.

MSCs are the main type of cell used in stem cell therapy. They heal and repair cells, secreting cytokines – immune system signalling and regulating proteins, growth factors, and exosomes – byproduct extracellular components.

It's these secretions that Regeneus CEO Leo Lee says are the differentiator behind their cell therapy technology, and allogeneic cell topical treatment platforms, and for which they received their first patent in 2011.

Regeneus has proven its technology and is months away from finalising a new partnership to distribute its knee osteoarthritis product. Inset: Regeneus CEO Leo Lee.

"When we first started treating people with their own stem cells, we noticed an onset of activity which couldn't be explained by the stem cells creating cartilage," says Lee.

"We postulated at the time, and found through research, that secretions including exosomes, added a lot of extra benefit.

"Further, and unlike cell mediated therapy, secretions doesn't involve live cells and are more stable, enabling a lot more treatment options."

Regeneus believes secretions which contain exosomes will be the future. One can think of exosomes as "the nuggets in chicken soup".

Lee says they improve viability and functionality of stem cells, a fact proven by the more than 3000 publications on the subject, and with others in the market now following in their footsteps.

With existing patents in Australia, the US, EU and Japan, Regeneus has recently received patent confirmation from the US and Europe, affording it commercial rights in the US and across 38 European member states until 2032.

The regenerative medicine market leader, and pivotal in the successful commercialisation of Regeneus' platforms, is Japan. Changing its clinical trial regulations in 2014 with its landmark Pharmaceuticals and Medical Devices Act and the Act on the Safety of Regenerative Medicine, Japan accepts "safety and probable efficacy", licensing early stage technologies which are proven safe in Phase 2 clinical trials.

"Japan offers a super highway for companies with technologies in regenerative medicine, allowing us to get to market with conditional approval," says Lee.

"This provides us earlier access to the Japanese market and from then on the funding and support for other filings in other parts of the world."

Fundamental to early commercialisation, however, is the in-licensing and partnership with Japanese corporations and universities.

Australian stem cell companies Mesoblast and Cynata have partnerships with JCR Pharmaceuticals and Fujifilm respectively.

Mesoblast's Temcell HS injection for acute graft versus host disease, a life-threatening complication of a bone marrow transplant, was the first allogeneic – sourced from a donor – cellular medicine to receive full approval in Japan.

Regeneus already has proven its technology by its licensing of cellular manufacturing know-how to a large Japanese drug manufacturer, AGC, part of the Mitsubishi group, and is months away from finalising a new partnership to distribute its knee osteoarthritis product.

> "Japan offers a super highway for companies with technologies in regenerative medicine."
> Leo Lee, Regeneus CEO

Once finalised, the company will refocus attention on its data packages for the US and Europe, set up its GMP manufacturing and continue with pre-clinical work and research in its other portfolio assets for pain and dermatology.

Lee says Regeneus is an exciting stem cell company with high potential, that is one Phase 2 study away from market. With the ability to drive significant value for shareholders, it is, at this point, undervalued.

Ausbiotech, Australia's peak biotech industry association's 2018 Snapshot of Stem Cell and Regenerative Medicine Companies in Australia, cites the perception of stem cell research as a risky investment, lack of strong Government funding and the small pool of specialist people with appropriate sector skills sitting on company boards as some of the hurdles facing stem cell commercialisation in Australia.

This month's appointments of John Chiplin, PhD and Alan W Dunton MD to Regeneus' board of directors addresses the skills hurdle.

"The addition of Chiplin and Dunton to the board and their proven successes in sourcing global capital and global drug commercialisation will be key in supporting Regeneus as it enters this next phase of growth" says Lee.

"I am confident of the significant value that will result from their strategic guidance and international connections."

Together with the pending Japanese partnership and published trials showing positive signs of disease modification and pain relief with longer lasting effects than morphine, Regeneus may well be one of the first to cross the stem cell finishing line.