

FOR A LIFE FREE OF PAIN

BY KAROLIS ROSICKAS, REGENEUS CHIEF EXECUTIVE OFFICER

REGENERATIVE MEDICINE COMPANY REGENEUS IS AT THE FOREFRONT OF PROVIDING A NOVEL, STEM CELL-BASED THERAPY FOR KNEE OSTEOARTHRITIS WHICH AFFLICTS HUNDREDS OF MILLIONS OF PEOPLE WORLDWIDE. THE COMPANY IS POTENTIALLY ONE CLINICAL TRIAL AWAY FROM GENERATING REVENUE FROM ITS LIFE-CHANGING TREATMENT IN ITS FIRST TARGETED MARKET: JAPAN.

ASX-listed Regeneus (ASX:RGS) is developing 'next generation' therapies to manage pain and inflammation. Around 1.5 billion people globally suffer from pain, and 50 per cent of patients report inadequate relief from existing therapies. Regeneus' primary focus is on knee osteoarthritis which affects 240 million people worldwide. The market for pain relief in this segment is estimated to grow to US\$3.5 billion by 2026. Regeneus' two proprietary platforms, injectable Progenza™ and topical application Sygenus, are unlike current therapies addressing these markets.

For example, traditional treatments for knee osteoarthritis, such as opioids and surgery, only treat symptoms, are invasive and can have serious side effects. Progenza™ is being developed to provide an alternative treatment for patients, avoiding side effects and promoting tissue repair through its disease modifying properties. Regeneus is now preparing for Phase II trials of Progenza™ in Japan and the US in 2022.

Meanwhile, Sygenus is being developed in partnership with the Australian Department of Defence as an alternative for morphine in the treatment of combat casualties, including treating pain, preventing blistering and accelerating wound healing.

"The ability to treat symptoms of pain, repair tissue and modify disease makes our Progenza™ technology unique," says Regeneus CEO Karolis Rosickas. "Given our strong IP position, with more than 80 patents, we're well positioned to deliver market-first treatments with Progenza™ and Sygenus."

The bioactive secretome of mesenchymal signalling cells (MSCs), also known as stem cells, is the cornerstone of Regeneus' technology. Progenza™ utilises a combination of MSCs and the secretome, while Sygenus is an MSC secretome-only based product.

MSCs and their bioactive secretome have powerful immunomodulatory effects, communicating with patients' resident tissue to repair damage and reduce pain and inflammation. For Progenza™, the bioactive secretome also improves the functionality and viability of the MSCs they are combined with by protecting the cells during manufacture and distribution.

Notably, through its highly scalable manufacturing process, Regeneus can produce millions of doses of MSCs from a single donor, reducing variability and lowering the cost of goods compared to other cell therapies.

In 2020, Regeneus signed a licence and collaboration agreement with Japanese manufacturer Kyocera Corporation to develop and commercialise Progenza™ for the treatment of knee osteoarthritis in Japan. The potential market in Japan is 25 million patients and is worth US\$330 million.

As the company prepares for Progenza™'s Phase II trials, Regeneus is getting closer to generating revenue. Japan's regulator, the Pharmaceuticals and Medical Devices Agency (PDMA), has an accelerated approval pathway for regenerative medicine therapies, and Regeneus deliberately targeted this jurisdiction so it could get to market faster and deliver value to patients and shareholders sooner.

"In Japan, we are one clinical trial away from selling our Progenza product in the market," says Mr Rosickas. "We expect to be in the market late 2024, early 2025 following successful filing and approval by the regulator."

The company is now exploring co-development and licencing options for Progenza™ outside Japan for knee osteoarthritis and other indications such as neuropathic pain.

"Our progress with both Progenza™ and Sygenus provides confidence that we are on the pathway to success," says Mr Rosickas.

