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Regeneus Q2 2016 Update

Dear <<First Name>> ,

Welcome to our newsletter for the quarter ended 30 June 2016.

Advancing partnering opportunities in Japan

In late May, members of the executive team visited Japan to advance discussions with potential manufacturing and commercial partners for Progenza in Japan. We are pleased to report our meetings went well and we are on track to enter into our first significant partnering agreement in Japan by the end of September 2016. We look forward to updating the market on this transformational opportunity.

We are seeing increasing interest in Japan from large healthcare and technology companies for cell-based regenerative medicine technologies. This interest has grown since the introduction in late 2014 of new regulatory changes by Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for an accelerated pathway to approval for regenerative therapies like Progenza.

[Read the interview](#)

REGENERATIVE MEDICINE IN JAPAN: CJ PARTNERS' COLIN LEE NOVICK ATHX, RP, RGS, 7774:TYO, 4527:TYO, 2372:TYO

Source: Gail Dutton of The Life Sciences Report (8/5/16)



Regenerative medicine is just beginning to be understood by governments and investors alike. Last autumn, new regulations took effect in Japan that promise to speed patient access to some of these new therapies. In this interview with *The Life Sciences Report*, Colin Lee Novick, managing partner with CJ PARTNERS, describes Japan's regenerative medicine frontier and lists investment-worthy companies that are pushing the boundaries.



The Life Sciences Report: Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has provided an expedited path to approval for regenerative therapies. How does that help propel Japanese regenerative medicine companies into the life sciences mainstream?

Colin Lee Novick: In terms of getting seed monies and technologies, the West has a much more vibrant venture capital environment, whereas Japan is heavily focused on university research. A lot of Japanese startups do preclinical and early clinical development studies at universities, Japan's equivalents to [clinicaltrials.gov](#), for instance, show that research institutes and national universities perform almost all regenerative medicine clinical trials.

Progenza development pathway

In May, we reported that the Progenza Phase 1 STEP trial for knee osteoarthritis (OA) is fully recruited without any unexpected safety concerns to date. This outcome has helped in the progression of our partnering discussions in Japan. The study will complete once the last patient completes 12 months post treatment follow-up concluding with a second MRI.

[Read the announcement](#)

We will move forward with the regulatory registration pathway in 2 jurisdictions. Our main aim is to progress towards GMP manufacture for a Phase 2 trial in Japan. This will include donor procurement, process development and technology transfer to our chosen GMP manufacturing facility. For the second jurisdiction (USA), we will complete some further preclinical studies (prior to submitting an Investigational New Drug (IND) application for a Phase 2 clinical study in the US). These studies will build upon the efficacy seen in our rabbit OA study. The results from the Australian Phase 1

STEP trial will also be helpful with the FDA pathway.

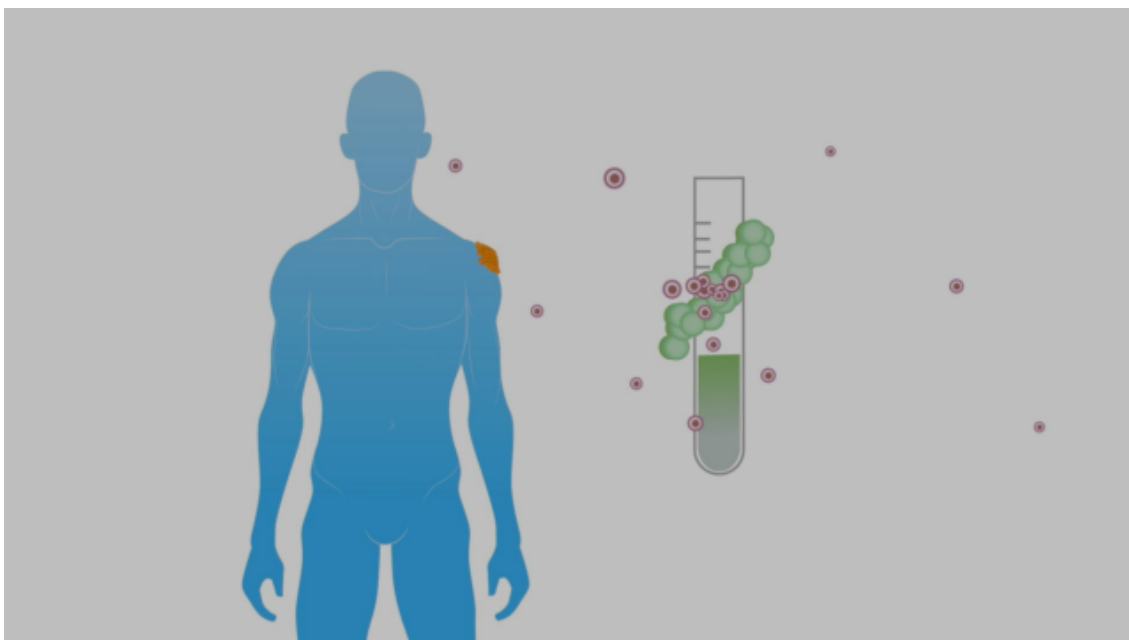


The rise of combination therapy of cancer vaccines and immune checkpoint inhibitors

RGSH4K, our cancer vaccine, belongs to a group of products called immunotherapies. These types of products work to stimulate the immune system into recognising and attacking tumour cells. RGSH4K is a vaccine made from a patient's tumour cells and administered back to the same patient to act on the cancer.

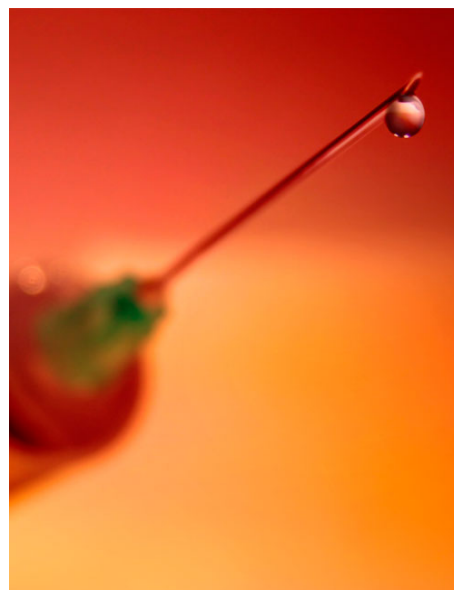
We have now recruited patients in each of the three cohorts for the ACTIVATE Study. This Phase 1 dose escalating study is evaluating the safety, tolerability and preliminary efficacy of RGSH4K and will treat 21 patients with advanced cancers.

We have opened a second tumour collection site and are seeing increasing tumour banking activity with a view to trial enrolment.



Via Cancer Research Institute on YouTube

Cancer is a complex disease but immunotherapy is an exciting area of research showing very good benefit to patients, significantly increasing survival over standard therapies. A promising group of immunotherapy products is called checkpoint inhibitors, some of which are approved and available for patient use. Checkpoint inhibitors act to 'release the brakes' and stop the cancer from blocking the action of the body's immune cells. Other therapies, such as cancer vaccines, work to 'step on the accelerator' to specifically focus the immune cells in a targeted attack against the cancer. Combining these types of therapies is giving even more beneficial results and is actively being tested in several cancer types.



[Learn more about RGS4K](#)

ARC Grant to explore using stem cells for chronic pain

In May, we announced the Australian Research Council (ARC) had awarded a Linkage Grant of \$340,000 to a research consortium that includes Regeneus collaborating with leading researchers from Macquarie University and the University of Adelaide to progress research into treating chronic pain with next generation stem cells.

[View the announcement](#)



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The changing biopharma risk equation

The changing biopharma risk equation is an Economist Intelligence Unit (EIU) report sponsored by Merck. It draws on a multinational survey conducted in March 2016 of 254 pharmaceutical executives. The report found that pharmaceutical companies are in an expansive mode. With rapid advances being made in the development of new therapies, including stem cell derived therapies and gene therapies, and a growing cohort of potential customers in the burgeoning middle classes of emerging markets, expansion into both new product categories and geographic regions is a priority for most companies.

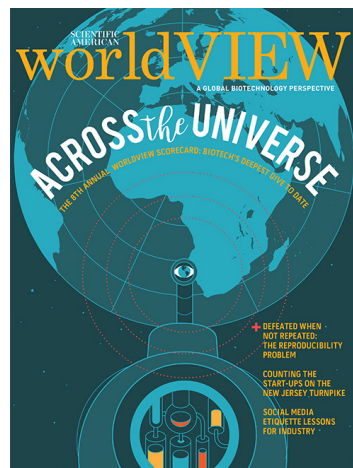


[Download full report](#)

Australia in top 5 for global biotech for 3rd year running

Scientific American Worldview: A Global Biotechnology Perspective has launched its eighth annual scorecard at the BIO International Convention in San Francisco, ranking Australia in the top 5 for the 3rd year running. Australia also produced the 12th highest output on the *Nature Index 2015 Global*.

[Download the report](#)



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