

TREATMENT FOR CHRONIC PAIN ATTRACTS MULTI-MILLION-DOLLAR DEAL

The acquisition of Spinifex Pharmaceuticals by the global pharmaceutical giant Novartis will bring a chronic pain treatment discovered at The University of Queensland a step closer to patients. It all began with the disclosure of an exciting research hypothesis to UniQuest in 2003.

Spinifex Pharmaceuticals, a biopharmaceutical company founded by UniQuest to commercialise a treatment for chronic pain, has attracted a multi-million-dollar deal - one of the largest in Australian biotech history.

In June 2015, the company was acquired by Novartis International AG for an upfront cash payment of \$US200 million (about \$A260 million), plus undisclosed clinical development and regulatory milestone payments.

The acquisition centred on Spinifex's lead candidate EMA401, a novel angiotensin II type 2 (AT2) receptor antagonist, being developed as a potential first-in-class oral treatment for chronic pain, particularly neuropathic pain. Having no or minimal central nervous system side effects, EMA401 is expected to have a competitive advantage over existing pain treatments in a market which is expected to be worth over US\$35B by 2017.

EMA401 is based upon research on the angiotensin II type-2 (AT2) receptor led by The University of Queensland's (UQ) Professor Maree Smith.

Through her research, Professor Smith first demonstrated that AT2 receptor antagonists reduced pain in animal pain models. This led Professor Smith to propose that a pain drug could be developed to act peripherally and overcome the central nervous system side effects of most current pain medicines.

GLOBAL POTENTIAL

The far-reaching global potential of Professor Smith's research was recognised by UniQuest from the very beginning.

In 2003 Professor Smith won the annual UniQuest Trailblazer competition, which identifies innovations that have the potential to benefit the community, industry or business. The innovation was then able to leverage the recognition gained from the Trailblazer award to attract grants to further the research.

Together, UniQuest and the researchers, Professor Smith and later Dr Bruce Wyse embarked on a journey to pursue research excellence, to protect the intellectual property and to form meaningful industry partnerships that would help take this breakthrough to the market.

UniQuest advised on the best patent strategy for commercialisation and, as a result and at its own cost, UniQuest sought to protect the innovation via patent applications - one covering neuropathic pain and the other inflammatory pain.

With the research showing encouraging pre-clinical outcomes and UniQuest's efforts in pitching the therapeutic opportunity to pharmaceutical companies and venture capital firms receiving interest, UniQuest was able to secure funds from a syndicate of three major biotech investors. The founding investors were GBS Venture Partners, Brandon Capital Partners and Uniseed.

The deal raised sufficient funds necessary for the vital next step – the toxicology program and human clinical safety trials.

UQ'S RESEARCH EXCELLENCE TO EXCELLENCE PLUS WITH UNIQUEST

UQ Research Strength:	Medicinal Chemistry and Pharmaceutical Sciences
UQ Innovator(s):	Professor Maree Smith
UQ Faculty or Institute:	Faculty of Medicine and Biomedical Sciences
UQ Research Outcome:	Novel and oral drug candidate for treatment of chronic pain
UniQuest IP Position:	Two patent applications which have issued in US, Japan, China, and Australia
UniQuest Partnering:	Pitch product opportunity to corporates and investors
UniQuest Commercialisation:	License IP to Spinifex Pharmaceuticals Pty Limited

SPINFEX PHARMACEUTICALS PTY LIMITED

COMMERCIALISATION STORIES

COMMERCIALISATION

In 2005, UniQuest formed the start-up company Spinifex Pharmaceuticals Pty Limited licensing the intellectual property rights in the patent applications to the company in return for equity and investment of A\$3.25 million from the investors. Both UniQuest and the investors took a position on the company's board.

Following the success of its Phase 1 clinical safety trials, Spinifex closed an A\$18.3 million series B capital raising in September 2011 to fund clinical efficacy trials of EMA401.

In April 2014, Spinifex completed a US\$45 million (A\$48 million) Series C financing led by Novo A/S and joined by additional new investor Canaan Partners. Existing investors GBS Venture Partners, Brandon Capital Partners, Uniseed and UniQuest also participated.

INTERNATIONALLY RECOGNISED EXCELLENCE

In February 2014 Spinifex Pharmaceuticals published results of its successful Phase 2 clinical trial of EMA401 in the prestigious medical journal *The Lancet*.

In a commentary published in the same issue, Dr Nanna Finnerup of the Danish Pain Research Center at Aarhus University described Spinifex's first clinical study as very encouraging, adding – "most importantly, their work identifies ... a novel mechanism of action, and offers hope for patients who have insufficient pain relief with presently available drugs."

"The success of Spinifex ... is a significant example of how an international venture capital syndicate, partnering with Australian based investors, can bring university technology closer to commercialisation."

Dr Heath Lukatch, Chairman - Spinifex Pharmaceuticals

ACQUISITION

In June 2015, Spinifex Pharmaceuticals announced that it had agreed to the sale of the company to Novartis International AG for an upfront cash consideration of US\$200 million plus undisclosed clinical development and regulatory milestone payments.

Dr Tom McCarthy, Spinifex's President and Chief Executive Officer said the acquisition was recognition of the advances Spinifex had made in developing EMA401.

"This acquisition by Novartis is a testament to the significant progress our team has made in developing an entirely new approach to the treatment of chronic pain and particularly neuropathic pain. We acknowledge the founding discovery and research carried out by Professor Maree Smith at The University of Queensland and we share Novartis' vision that EMA401, underpinned by our deep understanding of the AT2 receptor pharmacology, has the potential to be an important new treatment option for patients suffering from these debilitating conditions," Dr McCarthy said.

Novartis will continue the development of EMA401 and is planning to initiate Phase 2b clinical trials in patients with postherpetic neuralgia (PHN) or painful diabetic neuropathy (PDN).

PARTNER WITH UNIQUEST

UniQuest is one of Australia's leading research commercialisation companies. It specialises in global technology transfer and facilitates access for all business sectors to the world class expertise, intellectual property and facilities at The University of Queensland, Australia.

OUR TRACK RECORD

UniQuest enters into over 400 research contracts per year – many repeat clients from industry.

UniQuest has created over 70 companies from its intellectual property portfolio, and since 2000 UniQuest and its start ups have raised more than \$515 million to take university technologies to market. UQ technologies licensed by UniQuest – including UQ's cervical cancer vaccine technology and image correction technology in magnetic resonance imaging machines – have resulted in combined sales of final products in the order of \$11 billion net sales from 2007 to 2014.



If you want to know more about this commercialisation story or other offerings from Health and UniQuest, contact:

Dr Mark Ashton
Senior Director –Commercial Engagement, Health
Mobile +61 (0)410 601 970
m.ashton@uniquet.com.au or visit www.uniquet.com.au



THE SPINFEX JOURNEY

Professor Maree Smith
The University of Queensland

- Professor Maree Smith hypothesises that a pain drug could be developed to act peripherally and overcome the side effects of most current pain medicines which act on the central nervous system.
- The novel and orally available small molecule drug candidate is discovered by Professor Maree Smith in the Faculty of Health at UQ and dubbed EMA401 by Spinifex Pharmaceuticals.
- UniQuest files two patent applications and implements a commercialisation and partnering initiative culminating in a 2005 capital raising of \$3.25 million in venture capital.
- In 2011 Spinifex Pharmaceuticals closes an A\$18.3 million series B capital raising in to fund clinical efficacy trials of EMA401
- In 2011 Spinifex's development of EMA401 is recognised by Thomson Reuters as one of the "Top Five Most Promising Drugs Entering Phase II Trials".
- In 2012 Spinifex wins a BioSpectrum Editor's Choice Award.
- In 2013 EMA401 is chosen as one of the Top 10 Neuroscience Projects to Watch Worldwide.
- In 2014, Spinifex raises US\$45 million (A\$48 million) in a Series C financing.
- In 2015, Spinifex Pharmaceuticals is acquired by Novartis International AG for an upfront cash payment of \$US200 million plus undisclosed clinical development and regulatory milestone payments.