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# Spinifex Pharmaceuticals—Australia's Most Successful Venture Capital Biotech Exit

John Kurek, Peter Devine

**Abstract:** Spinifex Pharmaceuticals was a spin-off of the Australian biotech company Spinifex in 2014, which was a significant step forward in the development of a new treatment for chronic neuropathic pain. Today, its lead drug, EMA401, has been approved for use in the treatment of painful post-herpetic neuralgia and painful diabetic neuropathy.

**Keywords:** Spinifex, neuralgia, neuropathic pain, diabetic neuropathy

## 1. The success story – Spinifex

Over the past 25 years, there has been an extensive global research effort to understand neuropathic pain and develop new drugs for what is still a significant unmet clinical need. Current treatments such as opiates are addictive, and others such as gabapentin are repurposed psychiatric drugs that have side effects that are not effective in a significant number of patients. With their novel approach, Spinifex identified a pain receptor located outside the brain. Spinifex's lead candidate, EMA401, represents a potential first-in-class treatment for chronic neuropathic pain, without the side effects usually associated with drugs that enter the brain and the central nervous system.

## 2. The Journey so far

Spinifex is a University of Queensland spin-out company, established in 2005. The initial Series A investment round was led by Uniseed and Symbiosis, with GBS Venture Partners joining the round later that year. In 2008, these investors participated in a follow-on round and were joined by Brandon Capital Partners. In 2010 and 2012, Spinifex closed two following financing rounds to complete the preclinical development and the first-in-man clinical trials for their lead drug. The company also received support from Australian Government programs, including the Pre-seed Funds, Innovation Investment Fund (IIF), and Innovation Investment Follow-on Fund (IIFF), Commercial Ready, and the R&D Tax Incentive. In mid-2012, the company published positive results from their phase 2 clinical study in patients with painful postherpetic neuralgia (shingles), a study that was also published in the prestigious medical

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journal "The Lancet" <sup>1</sup>. The operations relied on an established virtual model with two full-time staff who were managing several external consultants to cover the preclinical, regulatory, and clinical aspects of the drug development program. To move to the next stage of clinical development, it was clear that significant additional funds would be required. To that end, in mid-2014, the company raised US\$45m in a Series C funding round from existing investors and top tier US VC's; Canaan Partners and Novo Ventures. The company also set up an office in Stamford, CT, to be closer to the pharma partners who would have an interest in the program. A larger management team led by CEO Dr Tom McCarthy was put in place, and preparations began for pivotal phase 2b studies in neuropathic pain conditions, while in the background, commercial discussions were also underway with potential commercial partners. This led to the deal in June 2015, where Spinifex was acquired by the Swiss multinational pharmaceutical company, Novartis. The deal included an upfront payment of US\$200m, providing significant multiples for the funds invested. In addition, milestone payments of up to US\$500m were also included in the deal. At the time, this was the most successful venture capital biotech exit in Australian history.



**Figure 1.** Professor Maree Smith (centre), with Johnson & Johnson Medical CEO Gavin Fox-Smith and AusBiotech CEO Dr Anna Lavelle.

### 3. Look into the future

Following the acquisition, Novartis continued developing EMA401 through two key Phase 2b clinical trials in patients with postherpetic neuralgia and painful diabetic neuropathy. However, the trials, which included clinical sites in Australia, were discontinued in early 2019. While this was incredibly disappointing, it does highlight the risk of drug development where only a small number of drugs that are discovered and developed actually reach the market. It takes time, requires resilience and perseverance, and a team of people with diverse skill sets all pulling in the same direction. We should also not forget the importance of the Spinifex deal (and the two others Uniseed has invested in—Fibrotech & Hatchtech) to the Australian biotech industry, which resulted in a return on investment capital to the sector and increased

Government support following several difficult years after the global financial crisis. In addition, scientists like Maree Smith should be celebrated as they serve as great role models for Australian scientists and open doors for others in the biotech and innovation sector.

### The company



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### References

[1] Rice A. S. C. et al., 2014. EMA401, an orally administered highly selective angiotensin II type 2 receptor antagonist, as a novel treatment for postherpetic neuralgia: a randomised, double-blind, placebo-controlled phase 2 clinical trial. *Lancet*. 383 (9929):1637-1647.

**John Kurek** is the Biotechnology Investment Manager at Uniseed, Australia's longest-running venture fund, operating at the Universities of Melbourne, Queensland, Sydney & New South Wales, and the CSIRO, with investment capital provided by these research organisations. At Uniseed, John is responsible for identifying new investment opportunities from the five research partners, and also covers



Uniseed's overall biotechnology and life sciences portfolio. Uniseed has returned significant capital to its investors, including Novartis acquisition of Spinifex for US\$700m; Shire plc acquisition of Fibrotech Therapeutics for US\$557m; and Hatchtech sale to Dr Reddy's Laboratories for ~US\$200m.

John brings 20 years of industry experience as a Biotechnology Manager with a focus on the strategic design and implementation of drug development programs. John's previous roles have been with ASX listed biotech companies BioDiem Ltd and Amrad Corporation Ltd., where he was responsible for the management of preclinical and early clinical stage drug development projects. His experience extends from late drug discovery to the phase I-II clinical phases of drug development. John's experience covers a range of areas, including 1) Acting as Director on investee company boards, 2) Biotechnology project management, 3) Investment analysis and due diligence, 4) Financial modelling, 5) Intellectual property management, 6) Business development, 7) Risk management, and 8) Relationship management.

John has a PhD in Neuroscience and a Post Graduate Diploma in Drug Evaluation & Pharmaceutical Science, both from the University of Melbourne, and is a graduate of the Australian Institute of Company Directors.

**Peter Devine** is CEO of Uniseed and has extensive experience at board and executive management levels in the commercialisation of early-stage technologies, having held senior R&D, business development and commercialisation positions in several Australian companies and Australian universities. Has served on the Board of numerous start-ups which have collectively raised over AU\$300m, with a number of these being successfully sold to large multi-nationals in deals collectively worth over AU\$1.75b.



Peter holds a PhD from the University of Queensland and received the Dean's Prize for his MBA studies at the Australian Graduate School of Management. He is a Graduate and Fellow of the Australian Institute of Company Directors and holds a Diploma of Financial Services (Financial Markets) and a Graduate Diploma in Applied Finance from Kaplan Professional. Peter was previously VP of Business Development at ASX-listed Progen Industries Ltd. He was Research, Development and Commercialisation Manager at Brisbane-based PanBio Pty Ltd from 1996 to 2000, which ultimately was sold to Inverness Medical. He received a Federal Government Centenary Medal in 2003 for outstanding contribution to the business of biotechnology.

Recent Uniseed successes include Fibrotech Therapeutics' sale to Shire in 2014; the Spinifex Pharmaceuticals sale to Novartis in 2015; the Hatchtech sale to Dr Reddy's in 2015 and FDA approval in 2020; the Smart Sparrow sale to Pearson on 2020 and Exonate's collaborative agreement with Janssen in 2020.