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# The Fibrosis Start-Up That Helped Put the Australian Biotech Scene on the Map

Peter Devine

**Abstract:** Fibrotech, a Melbourne-based biotech start-up, that was formed in 2006 to develop novel drug candidates for the treatment of fibrosis, prevalent in chronic kidney disease. In 2018, Fibrotech was re-established as Certa Therapeutics to support Phase II clinical trials for the lead candidate, FT011.

**Keywords:** Fibrotech, fibrosis, kidney disease.

## 1. The success story—Fibrotech

Prevalence of kidney disease, and thereby fibrosis, continues to increase as the population ages, with treatment costing approximately US\$1b of annual healthcare expenditure in Australia alone. Fibrotech developed a chemical compound that could effectively reduce scar tissue as a potential treatment for fibrosis. At these early days of biotech growth within Australia, support for Fibrotech was sparse despite there being clinical demand in the space where the global estimate value was \$5b.

## 2. Where did it start and the motivation?

In a University of Melbourne lab, an idea to treat kidney disease sufferers and potentially prevent fibrosis or scar-tissue was born. Prof. Darren Kelly and his team at the university were working on a compound which was shown to have anti-scarring and fibrotic effects in the kidneys and heart. In collaborating with chemist Spencer Williams, Kelly was able to develop the medical chemical programme enhancing the efficacy of the compound, effectively reducing scar tissue as a potential fibrosis treatment. However, due to patenting issues, the compound could not be progressed.

Kelly spent 18 months raising money for the fibrosis treatment he knew had huge potential. After rounds of disappointing meetings, UniSeed made an initial commitment to Fibrotech, and the MRCF joined in the first round of funding. Dr Chris Nave of the MRCF and Dr John Kurek from Uniseed joined the Fibrotech board. "We were impressed with Darren and his understanding of the market and the disease. He was a rare individual—both a great academic researcher, but also capable of leading the company as CEO".

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**Peter Devine:** Uniseed, Brisbane, Queensland, QLD Australia

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### 3. The journey so far

In 2007, support mechanisms were thin. Ann Hamer, COO, and Kelly relied on the networks of UniSeed and the MRCF to progress the drug, and the sole founder was responsible for fund-raising. In 2009, in an Australian first, Fibrotech was awarded a Type 1 Diabetes RAID Grant from the US National Institute of Health. This in-kind grant from the US was a milestone for the Australian biotech landscape. This opportunity awarded Fibrotech much leverage. Despite pressure from US VC firms to bring the company stateside, Kelly was adamant the company would remain in Australia. Companies now have resources available in Australia, such as R&D tax concessions, allowing them to complete later stage clinical trials in Australia without the need to move to the US. Fibrotech helped shape the biotech industry in Australia as we know it today.

With no real team and a small budget, Hamer and Kelly worked with a revolving door of consultants to advance the lead drug to clinical trials. Fibrotech Therapeutics' 2014 deal with UK pharmaceutical company, Shire, was revolutionary, leading to a positive shift in the investment sector. This deal, valued at over US \$500m, showcased the huge returns that university-generated start-ups could deliver and validated Australian biotech research. The deal was named "Best Early Stage Deal of the Year" by AVCAL in 2014, and the exit was recognised as a game-changer by the prestigious journal *Nature*.



**Figure 1.** Certa Therapeutics chief executive and founder Darren Kelly, front, with (left to right) Emile Brys, chief commercial officer; Ann Hamer, chief operating officer; Dr Chris Nave, Medical Research Commercialisation Fund chief executive; John Kurek, Uniseed investment manager; Michelle Papadimitriou, research and development manager.

UniSeed's first blockbuster exit, Fibrotech was a significant deal to the fund—returning US\$75m to shareholders the MRCF and Uniseed. Shire then committed to completing a Phase 2 program with Fibrotech's lead drug FT-011. However, in 2016, Shire acquired Baxalta and subsequently advised that they were discontinuing the Fibrotech program. Shire terminated

over 100 early-stage programs, of which Fibrotech was a casualty. Fortunately, Shire returned the new drugs and data they had developed to former Fibrotech shareholders. This enabled the development program to continue in a new company supported by Fibrotech investors Uniseed and MRCF, with Kelly returning as CEO. Fibrotech was re-established as Certa Therapeutics in 2018, with \$25m raised to support Phase-2 studies.

#### 4. Look into the future

Fibrotech generated a groundswell of interest in the potential of university research, while the Australian economy improved following the Shire deal. University entrepreneurship has now become fashionable, and superannuation funds have returned to support venture capital. The Government has also become more supportive, with schemes such as the Biomedical Translation Funds introduced in December 2016 on the back of Fibrotech's success.

Certa now has a fantastic team of over ten experts, and the landscape has drastically changed. The larger team enables better long-term collaboration, and Kelly learned through his networks the importance of having robust technology management, when to hire or to outsource, and when to engage with clinical research organisations. The collaborative benefit of having a team versus consultants allowed the promising Australian biotech start-up to remain in Australia, conduct its research and development here, benefitting the Australian economy, and ultimately creating jobs.

Now Certa is about to go into Phase II clinical trials for two indications, including lead candidate FT011 with hopes to have this oral therapy for the treatment of fibrosis on the market within five years.

#### The company



Fibrotech Therapeutics Pty Ltd  
Level 9  
278 Collins Street  
Melbourne  
VIC 3000  
Australia  
[www.fibrotech.com.au](http://www.fibrotech.com.au)

#### References

[1] *Nature* (V557, S28, 10 May 2018).

**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.