



Biotech Daily's CEO interview

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STARPHARMA'S DR JACKIE FAIRLEY - LEADER OF THE DENDRIMER PACK

Dr Jackie Fairley comes from a medical family. Her grandfather and all his brothers were doctors. Both parents were doctors. Mum, Prof Priscilla Kincaid-Smith, ran the Royal Melbourne Hospital's renal unit. Both brothers Kit and Stephen are doctors and husband Ian Fraser works at Mum's alma mater.

So with a world open to her after graduating as one of the first girls at Geelong Grammar she chose to study Science and later Veterinary Science.

It wasn't the first sign of individualism and determination. Aged 10 she told her Melbourne-residing parents that she wanted to go to boarding school, a path generally forced on country children and those whose parents were overseas.

Jackie started at The Hermitage in Geelong, which amalgamated with Geelong Grammar in 1976. On holidays at the family farm, Jackie survived riding her trail bike up and down the steep hills of the Otways. She says she was a better rider than a pillion passenger.

From school she started her BSc at the University of Melbourne, aged 16, majoring in pharmacology and pathology.

"I didn't want to do research. I was accepted into Medicine and Veterinary Science and was a bit rebellious, so coming from my family, I did Veterinary Science!"

General practice with Armadale's cats and dogs was "a bit like a cross between being a carpenter and a seamstress" and the surgery required a dexterity she felt she didn't have.

She married renal specialist Dr Ian Fraser in 1988 and the following year made the jump to working in regulatory affairs at the then Commonwealth Serum Laboratories, now CSL, where she worked on developing recombinant proteins. While at CSL she began her Masters of Business Administration at the Melbourne Business School where she was somewhat shocked by the overt sexism from some staff and fellow students, who retained prehistoric notions that women "couldn't do finance" and "didn't belong on boards".

It was a stark contrast to science where outcomes were more measurable and women were in far greater numbers.

Despite winning the 1992 Clemenger Medal for topping her class she was not recommended by her lecturer for a job at a leading bank. Nor were any of the other three women in the top eight of the year. Eight males were recommended to the bank.

In her acceptance speech, Jackie noted the discrimination in the nicest way. Just 20 percent of the MBA intake were women. The last three Clemenger Medal winners were all women.

“The outputs of science are more easily measurable,” she says. “There are more women in science than business.

“I loved the MBA. It was an incredible amount of work. I got a whole lot of academic prizes and the fees were not cheap, but I think I made a profit on it.”

She went back to CSL as a business development manager and in 1994 joined Faulding in the same capacity developing injectable oncology products, prior to taking over as head of the regulatory group.

Along the way she had two children, James and Sophie.

“When I left in 2000, the group had 120 staff in global product development which included working with the FDA and work on generics.”

For six months she worked on a venture fund but was approached by Geoff Brooke (GBS Ventures) and Michael Panaccio (Starfish Ventures) to join Cerylid as CEO, screening Australian flora and fauna for novel drugs.

She was appointed Starpharma’s chief operating officer in March 2005 and replaced Dr John Raff as CEO on July 1, 2006.

Jackie Fairley pauses after an hour of conversation to point out that the interview had concentrated on her and not her company. She wants to talk Starpharma and Vivagel, not about herself.

She compares Vivagel to other microbicides and says it is difficult to comprehend how Carraguard managed to get to a phase III trial while showing little if any efficacy.

“Vivagel is one of the few microbicides that work. It is one of the best performing in vitro and in vivo animal studies,” Dr Fairley says.

“I’m not really surprised Carraguard failed. It wasn’t very potent in vitro and not at all in vivo and went all the way to phase III trials and it’s hard to find the data,” she noted.

Vivagel’s active ingredient SPL7013 appears to be potent against HIV, herpes simplex virus 2 (HSV-2), as well as a contraceptive. It is in development with two condom manufacturers as a coating to replace nonoxynol 9.

But the Vivagel plastic applicator has been questioned on cost, ease of use and its environmental impact, particularly for the developing world, where poverty and AIDS are great concerns.

It is an uncomfortable subject for Jackie Fairley. She says a measured dose is required deep in the vagina, apparently disallowing its use as lubricant gel. Even in US trials, non-compliance has been an issue.

For those who do comply with Vivagel there are multiple benefits. Jackie Fairley says 30 to 50 percent of “all new HIV infections in Africa” are due to prior infection of HSV-2, which causes lesions making people more susceptible to HIV infection.

But Starpharma’s lead product is just the first application of an entirely new delivery platform.

Dr Fairley says dendrimers are synthetic large spherical molecules, are made up of a series of layers and the surface can hold different drugs.

“They are versatile and can be drugs in themselves. Vivagel is a dendrimer as a drug in itself.

“The surface is made up of anti-viral groups binding to receptors on the surface of a virus rendering it incapable of binding to human cells.

“Dendrimers can be versatile like silicone,” she says.

Dr Fairley said the November 2006 takeover of the US based Dendritic Nanotechnologies (DNT) was a perfect fit because the two companies had been working in parallel and in collaboration since 2002.

The acquisition brought the Dow Chemical Company on board as a major investor. She says the DNT deal with Dade Behring has dendrimers in Dade Behring’s Elisa test kits orienting the antibody and making them “much more sensitive and specific with fewer false positives and fewer false negatives”.

Dr Fairley said dendrimers can be used for novel drugs but can also be used to enhance existing drugs, which also made them a delivery device.

In pre-clinical work dendrimers loaded with an anticancer therapeutic can be injected intravenously. They travel to the tumor and become concentrated and then release their anti-cancer drug.

“This is a really valuable application of the dendrimer platform,” she said.

She says acquiring DNT gave Starpharma a commanding lead in developing the technology.

“We have a really dominant IP portfolio that includes more than 100 patents and Dow’s entire dendrimer portfolio, in which they invested about \$40 million.

“We are the only company to take dendrimers to the clinic and we are the only company that can make the material in a pure enough and reproducible form to meet FDA requirements.

”There are other academic groups and some researchers in large pharmaceutical companies, but we are definitely the leader in terms of numbers of patents, deals and portfolio.”

Starpharma fell one cent or 2.99 percent to 32.5 cents.