

CSIRO spin-off Benitec raises \$7m for hep C treatment after six-year patent war

Published 17 June 2013 11:36, Updated 17 June 2013 12:45



“The most complex and has the most exciting potential of anything I’ve seen in my last 35 years of medical research”: Benitec founder Peter French

CSIRO spin-off Benitec Biopharma has emerged from a six-year patent battle in the US, and is set to begin clinical trials on potentially lucrative treatments for hepatitis C and other currently incurable diseases.

Benitec this month completed a \$7 million capital raising. Days later, its hepatitis C therapeutic treatment TT-304 was given the go-ahead for human trials by the US National Institute of Health’s Recombinant DNA Advisory Committee. The final roadblock is getting approval from the US Food and Drug Administration.

The company’s patented gene-silencing technology was developed by the CSIRO in the late 1990s and has since formed the basis for more than 100 patent applications. Similar technology developed simultaneously in the US led to a Nobel prize in medicine and physiology to US researchers Andrew Fire and Craig Mello.

But a gruelling battle with another biotech company – Nucleonics – triggered subsequent legal roadblocks that curbed Benitec’s hopes for years. Nucleonics went into liquidation in 2008 and it wasn’t until October 2010 that Benitec’s patents were ticked off by the US Patent and Trademark Office’s Board of Appeal.

“For six years we were lying dormant,” says Benitec CEO Peter French. “In terms of an emerging company, we really started life three years ago.”

Patent rows are part of life in the biotech sector, illustrated most recently by the top US court’s decision to block patents on breast cancer genes. But Benitec’s own litigious approach to its competitors is widely blamed for the six-year detour.

Benitec owns the patents for gene-silencing technology, known in biotech jargon as ddRNAi, which shuts down genes such as those associated with the production of diseases. A CSIRO team, including Benitec founder Mick Graham, came across the phenomenon in the late 1990s when researching plants.

French, who joined Benitec in mid-2010, says Benitec’s technology is “the most complex and has the most exciting potential of anything I’ve seen in my last 35 years of medical research”.

“It has the potential to turn off any gene associated with any disease,” French says.

“If the liver fails due to hepatitis C, the only course of action is a liver transplant. This treatment has the ability from a single injection to eradicate the virus from the liver, and to sit there and guard against reinfection.”

He says it has been “highly effective in the lab”.

The coming year is an exciting time for Benitec. It acquired US-based Tacere Therapeutics, which was licensing its technology, in October last year. Tacere hopes this year to trial its hepatitis C treatment in patients who have failed all levels of care and have no options left.

Calimmune, another US licensee, is also hoping to start clinical trials for an HIV treatment using the technology, while lung cancer treatment trials will begin in Europe next year.

If it's all successful, needless to say it's lucrative technology. French is reluctant to give numerical estimates. “Hepatitis C therapeutics have attracted a lot of interest from big pharma in recent years,” French says. He names the acquisition of Pharmasset by Gilead for \$10.8 billion in late 2011, and the Bristol-Myers Squibb acquisition of Inhibitex for \$2.5 billion around the same time. Both acquired companies were developing hepatitis C treatments.

“This is a great Australian story, if it works,” French says. “We're about to be at the point where we prove it one way or the other.”

Marc Sinatra, a life sciences analyst at Melbourne-based Lodge Partners Research, has given Benitec a “buy” recommendation and a 12-month price target of 3.2¢ per share, up from its current 1.3¢.

“There's always a reasonable amount of risk in any stock that is in pre-clinical or early clinical stages,” Sinatra says. “The Benitec science is extremely well nussed out, and Michael Graham, the discoverer of the technology, was very unlucky not to win a Nobel prize that was ultimately awarded to Fire and Mello for RNA interference.”

He says the sector was always going to be a legal minefield but Benitec could have stayed out of trouble by not taking such a litigious approach itself.

“Benitec probably wouldn't have had any problems if they had not chosen to start suing people who were possibly infringing their patents,” Sinatra says.