



Biotech Daily

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Dr Boreham's Crucible: Innate Immunotherapeutics

By TIM BOREHAM

ASX code: IIL

Market cap: \$175 million; **Share price:** 76.5 cents; **Shares on issue:** 224 million

Chief executive officer: Simon Wilkinson

Board: Michael Quinn (chairman), Andrew Sneddon, Elizabeth Hopkins, Chris Collins, Dr Robert Peach, Simon Wilkinson

Financials (December quarter 2016): revenue nil, cash burn \$1.78 million, cash balance \$6,016,000* (down 22%), estimated current quarter cash outflows \$2.15 million

* Ahead of March placement that netted \$2 million

Shareholders: Chris Collins 17%, Australian Ethical 4.8%, Caitlin and Cameron Collins 2.34% each (4.7%), founders (combined, 3.6%), National Multiple Sclerosis Society of the US (1.6%)

Most Australian biotechs yearn for recognition on the global stage and in the real corridors of power. But for the secondary progressive multiple sclerosis (SPMS) drug developer, it's a case of a cabal of influential US Republicans loving the stock a little too much for comfort.

At the risk of repeating the wide reportage on the matter, Innate's biggest shareholder (and a director) Chris Collins is a New York congressman who sits on the health subcommittee of the House Energy and Commerce committee.

He is also President Donald Trump's congressional liaison and one of the first to endorse Mr Trump for the presidency, which was a lonely position within the GOP at the time.

Dr Tom Price, Mr Trump's pick as Health Secretary, also owns shares acquired when he was a member of the House ways and means sub-committee.

This transaction reportedly was being probed by Preet Bharara, the US attorney for the southern district sacked by Mr Trump.

Along with several other Republicans of note, Dr Price's chief of staff Michael Hook and fellow former NY congressman Bill Paxton (not to be confused with deceased actor Bill Paxton) also took a shine to Innate shares.

Rightly or wrongly, the implication is that Innate might enjoy some sort of a free ride when it comes to its yet-to-be-approved SPMS compound, MIS416.

Mr Wilkinson and Mr Quinn say they do not even know most of the gentleman concerned, a key exception being board member Mr Collins.

Mr Wilkinson also told the New York Post the company had no interest in gaining the ear of Washington's heavy hitters, because its primary goal was to strike a partnership with a big pharma partner.

"It won't be up to us to seek approval for the drug."

On a related front, the Takeovers Panel last month rejected a claim that Mr Collins in effect controlled Innate because he was associated with family members and other shareholders.

Citing a lack of evidence, the panel accepted that Collins children Caitlin and Cameron -- who hold just under 5% in their own name -- won't be told what to do by their old man.

As a father of two teenagers, Dr Boreham knows the feeling.

Er, where were we?

Coming back to MIS416, the compound is a micro-particle that targets both the regulatory and defensive functions of the immune system. The company derives its name from innate immune systems, the first line of defence against external pathogens and internal disorders such as cancer.

From late 2014, 93 patients were enrolled in a placebo-controlled, randomized phase IIb trial targeting safety and efficacy. The last 16 patients are due to complete the study in one month, with top line results due in April ahead of a full clinical report in August or September.

While there are more than a dozen multiple sclerosis drugs of varying efficacy, there is currently no approved treatment for SPMS. About 30 percent of multiple sclerosis patients develop to the SPMS stage, presenting an unmet \$US7 billion a year market.

Management is supremely confident of positive results, citing “strong evidence of safety and likely efficacy” from prior trials (phase I and IIa), as well as the use of the drug in a New Zealand compassionate use program for the past seven years.

So far in the phase IIb trial, 90 percent of patients have applied for on-going access to the drug.

The company also boldly states it “expects” a corporate transaction later this year, following the release of the results.

Prospects:

Innate shares have fared more erratically than Mr Trump’s policy positioning, having attracted an ASX query after zooming from 83 cents a share pre-Christmas to a January 25 high of \$1.83.

The company posited that media coverage here and in the US “may also have generated increased in the company’s prospects”.

Who was it who said any publicity is good publicity?

The shares have tanked since, although put in context the stock traded at 20c a year ago.

Dr Boreham’s diagnosis:

We will assume Innate-gate is more a US domestic issue about the probity of these heavy-hitters holding Innate shares, rather than a controversy likely to embroil the company itself.

Thus, Innate’s fortunes will prosper or founder on the strength of the upcoming trial results.

In a company-commissioned report, Gordon Capital values Innate at \$1.81 to \$3.63 a share. This assumes MIS416 achieves a 20 to 40 percent market share by year three, with an earnings before interest taxation and amortization (Ebitda) margin of 30 percent.

But the outcome is binary: MIS416 must work and the company is not presenting a plan B.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Nor does he have White House contacts but he does know someone who met the Donald at a party in the 1980s and there was no pussy grabbing at all.