



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Innate Immunotherapeutics

By TIM BOREHAM

ASX code: IIL

Share price: 31 cents

Market cap: \$12.7 million

Shares on issue: 41,022,907*

Chairman and chief executive officer: Simon Wilkinson

Board: Simon Wilkinson, Dr Robert Peach, Andrew Cooke (company secretary), Dr Chris Behrenbruch, Dr Warwick Tong, Dr Christopher Burns

Departing directors: chairman Michael Quinn, Andrew Sneddon, Elizabeth Hopkins and Chris Collins

Financials (March quarter 2018): revenue nil, cash burn \$550,000, cash balance \$2.2 million, expected June quarter cash burn \$347,000

* After 10-to-one consolidation of existing 225 million shares on issue and issue of shares to Amplia.

Welcome back – we never expected to see you around these parts again!

The Auckland-based Innate looked a goner after its proposed multiple sclerosis treatment MIS416 spectacularly failed a phase II trial a year ago.

Now, Innate has emerged as an oncology-focused house with the rights to two pre-clinical immunotherapy assets.

In fact, all the changes are expected to be finalized today, Friday May 4, showing how prescient or serendipitous this column can be.

At an extraordinary meeting on April 26, Innate holders waved through the company's proposal to purchase Amplia Therapeutics. Amplia is a private Melbourne outfit that has the rights to two potential drug candidates targeting focal adhesion kinase (FAK) inhibitors.

Amplia is owned by parties including biotech man-about-town Dr Chris Behrenbruch, scientist Dr Chris Burns and Peter MacCallum Cancer Centre researcher Mark Devlin.

After MIS416 flopped, Innate had nowhere to go - and management admitted that in a rare outbreak of candor for the sector.

Rather than slicing and dicing the trial data to contrive a better result, the board swiftly curtailed activity to preserve funds and went in search of another pursuit.

Given MIS416 is a micro-particle targeting the regulatory and defensive functions of the immune system, the acorn hasn't fallen too far from the tree.

In fact, Innate was doing preclinical work on immune-oncology between 2004 and 2008 - well before it became sexy with investors and big pharma.

"If anything, the tree has moved close to the acorn," says Innate chief executive officer Simon Wilkinson.

Amplia in a nutshell

The Amplia deal sees Amplia holders emerge with 45 percent of the new Innate, or 18.5 million new shares. The existing 225 million shares were consolidated to 22.5 million shares.

Amplia has licenced the assets from Cancer Research UK, with a patent life to 2033.

The program was initiated by the Melbourne based, Federal Government-funded Cancer Therapeutic Cooperative Research Centre.

Cancer Research UK is entitled to milestone and royalty payments, which Innate expects will not exceed \$200,000 over the next two years.

Mr Wilkinson says the company kissed between 15 and 20 frogs before settling on Amplia from a short list of three to five serious prince candidates.

"Some of the frogs we batted away after one phone call and some were looking to back-door list new technologies that had nothing to do with biotech," Mr Wilkinson says.

Trump man remains supportive

The new board sees Mr Wilkinson continue as both chief executive officer and chairman. Dr Robert Peach, who led the due diligence on the acquired assets also remains. Dr Behrenbruch, Dr Burns and Dr Tong and Mr Cooke join the board as Amplia reps.

A notable board departee is Chris Collins, US President Donald Trump's congressional liaison who held 17 percent of the old Innate and heavily spruiked the multiple sclerosis program in country club Republican circles. Dr Tom Price, Mr Trump's pick as US Health Secretary, also received a private placement in the stock.

Innate-gate raised more than few eyebrows around Capitol Hill, to say the least, but the kerfuffle eventually died down as The Donald offered up bigger controversies.

Mr Collins meanwhile remains a true believer in Innate.

"He has not sold a single share and is fully supportive of the acquisition and moving into oncology," Mr Wilkinson says.

In fact, post the dilution, Mr Collins remains one of Innate's biggest shareholder with a 9.35 percent stake, with Cancer CRC subsidiary CTEXT Pty Ltd holding 11 percent.

What the FAK?

FAK, we stress, should not be confused with Graham Kennedy's famous crow call (especially with a Kiwi pronunciation).

Rather, FAKs are a target because they regulate the way cancer cells hide from the immune system and thus survive and prosper.

Innate expects at least one of its two candidates, AMP886 and AMP945 to be used in combination with other immunotherapies when the single-agent approach hasn't worked.

Technically speaking, a FAK could be synergistic with checkpoint inhibitors targeting other cancer indicators such as mTOR, SRC and BRAF.

FAK is also implicated in fibrotic diseases, which raises hopes of using the compounds to treat a range of non-cancer ailments.

Innate says the "highly attractive" FAK candidates show "excellent potency and drug like properties, biological selectivity, bio-availability and manufacturing scale-up potential".

The programs are in pre-clinical stage, "but there is a considerable body of data from the pre-clinical cancer models run to date that point to efficacy".

At least one of the drug candidates is expected to be ready for phase-one testing on healthy volunteers within about 12 months.

Innate draws parallels with the Nasdaq-listed Verastem (market cap \$300 million) which is undergoing FAK combination trials with the heavy-hitting Merck and Pfizer. Targets include pancreatic, ovarian, non-small cell lung cancer and mesothelioma.

Innate contends Amplia's assets are "superior in terms of biological properties and target selectivity".

Prospects and performance

Innate shares vaulted 300 percent after the Amplia deal was unveiled on March 23, but have settled back to where they were.

In March, Innate suffered the opprobrium of being chucked out of the All Ordinaries index, which was a bit, well, ordinary. Investors value Innate at around \$14 million, a far cry from the old Innate's peak value of \$700 million in early 2017.

Innate says its cash balance of \$2.5 million is enough to last 12 months, but the company expects to raise capital for the phase I testing "in due course".

Meanwhile, there's still potential value with MIS416, which remains on the books, as a cancer drug. While Innate focused on multiple sclerosis, the molecule was supplied to collaborative oncology research programs in Japan and the US.

"We haven't made a song and dance about it, but we never turned our back on cancer," Mr Wilkinson says.

Dr Boreham's diagnosis:

When Dr Boreham subjected Innate to the searing heat of the Crucible in March last year, he cautioned (somewhat self-evidently) that Innate's fortunes would prosper or founder on the strength of the multiple sclerosis trial.

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

Happily, Innate now does have a plan B but we caution (just as self-evidently) that it's very early days. In the next one to three months the company will release details of its clinical program and, presumably a capital raising.

But at least the company has regained a purpose in life.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But rest assured, he does give a FAK about the sector.