



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Prima Biomed

By **TIM BOREHAM**

ASX code: PRR

Nasdaq code: PBMD

Share price: 3.0 cents; **Shares on issue:** 2,362,662,532; **Market cap:** \$70.9 million

Chief executive officer: Marc Voigt

Board: Lucy Turnbull, Albert Wong, Marc Voigt, Dr Russell Howard, Pete Meyers, Grant Chamberlain

Financials (September quarter): receipts \$1.3 million, operating cash outflow \$726,000, cash balance \$16.95 million (previously \$12.3 million), estimated current quarter outflow \$4.3 million

Identifiable shareholders: Thomas Tscherepko (1.1 percent), Marc Voigt 1.03 percent, Frederic Triebel 0.88 percent, Lucy Turnbull 0.86 percent.

(There are no substantial shareholders, but the annual report says that Mr HSBC Custody Nominees owns 37.1%, of which the Miami Beach Wayne Holman and Ridgeback Capital are believed to own about 5%.)

Mr Harbourside Mansion may be accused of a lack of empathy when it comes to the common folk but there's no lack of this quality on the Lucy Turnbull-chaired Prima Biomed board.

“Regarding our recent share price performance, your board and management team are acutely aware of this and share in the frustrations of shareholders given the recent flow of positive company news,” she said in the annual report.

Lucy’s \$150,000 a year Prima role survived a probity review before hubby Malcolm deposed Tony Abbott as PM, but she had to scuttle her directorship of ferry operator Sealink and bid auf wiedersehen to the board of the German-Australian Chamber of Industry and Commerce.

Lucy owns a decent wad of Prima shares herself and happily for the stretched Turnbull family budget Prima shares in early October rallied from near lows of 2.2 cents to as high as 4.0 cents (briefly and on no real news).

Still, it’s cold comfort for Prima holders who have seen the company consistently defy expectations ever since morphing out of Prima Resources in the early noughties.

The shares peaked at 42 cents in 2011, following some very interesting day-trader activity in the Global Financial Crisis that pumped the company from half a cent in January 2009 to 1.6 cents by April 13 and the big jump to 11 cents by April 20, 2009.

Changing course

Having originally focused on the CVac ovarian cancer vaccine, Prima Biomed these days is all about the sexy but still largely unproven field of cancer immunotherapy.

A year ago, Prima sold CVac to a New York based former online advertising company called Sydys, in a deal worth up to \$400 million in milestones and royalties.

This was after Prima’s phase II ovarian cancer trial flopped in September 2014.

The \$400 million sounds superb, but there’s a catch: the deal didn’t involve cash but a 10 percent stake in the impecunious Sydys, which had about \$US800 in the bank.

That’s correct – not \$US800 million or even \$US800,000, but just an old-fashioned \$US800, almost enough for a one-way flight to New York in peasant class.

At last report Sydys, which is listed on the US over-the-counter market, was seeking to raise funds for further clinical trials.

However recent ovarian cancer trial setbacks elsewhere are thought to have made the task a tad difficult.

In a cleansing prospectus in relation to a proposed issue of warrants, Prima says: “As Sydys possessed no significant cash reserves at the time of the transaction and generally lacks product diversity, there are significant risks associated with this transaction.”

Chief executive officer Marc Voigt says: “We wish them well. But if nothing comes of it at least there’s no downside for us.”

New aim, new name

Prima’s new immunotherapy stuff was acquired via the takeover of the French biotech Immutep in 2014 for up to \$US28 million. Given Prima is now all about the acquired portfolio, the company proposes changing its name to Immutep at its November 17 AGM.

Makes sense

The technology revolves around a protein called lymphocyte activation gene-3 (LAG-3), a so-called checkpoint inhibitor.

LAG-3 was discovered in 1990 by Immutep’s scientific founder Prof Frederic Triebel, now Prima’s chief scientific officer.

Without getting too sciencey, LAG-3 is of great interest as an agent that regulates T-cell immune responses.

Immune checkpoint inhibitors account for about 70 percent of the market for cancer immunotherapies.

Prima’s lead candidate, IMP321, is a soluble form of LAG-3. It is hoped that by being directly injected into the tumor it will activate the antigens present in the cells to boost immune response.

Prima has early stage clinical programs underway for metastatic melanoma and breast cancer.

Management reports recruitment is progressing well, with Prof Triebel due to present melanoma data to the World Immunological Congress in Basel on October 31.

The company also has coveted poster presenter status at the Society for Immunology of Cancer pow-wow, to be held in Maryland on November 10.

Prima is recruiting in Europe for a phase IIb, 226-patient, metastatic breast cancer trial called AIPAC, which combines IMP321 with chemotherapy drug paclitaxel (sold as Taxol).

Recruitment is also underway on a combination drug phase-one skin cancer trial called TACTI-mel, as in Two ACTIVE Immunotherapeutics in MELAnoma (gettit?)

The trial combines IMP321 with Keytruda, a.k.a. The Drug That Saved Businessman Ron Walker.

“Based on our current assumptions, the 22-patient trial should be fully enrolled by the end of the first half of calendar 2018,” Prima says.

First data on progression-free survival is expected “as early as the first half of calendar 2019”.

Take your partners

In buying Immutep, Prima inherited some big-ticket big pharma support for its programs.

Under licence from Prima, Novartis (formerly Co-Stim Pharmaceuticals) has the developments rights for IMP701, an antagonist (blocking) antibody targeting the LAG-3 molecule on T-cells.

Named LAG525 by Novartis the program has generated modest royalties for Prima (the company received a second payment of \$US1 million in August).

The program is subject to phase I/II studies at 13 different locations.

Prima says that according to “certain publicly available records” Novartis increased the number of patient enrolments from 240 to 416 in the 2016 financial year.

Prima is also in bed with Glaxosmithkline, which has the global rights to an antibody called IMP731.

Glaxo’s investigational product (derived from IMP731) “aims to kill the few activated LAG-3 T-cells that are autoreactive in autoimmune diseases, leading to long-term disease control without generalised immune suppression”.

In effect, it’s all about suppressing overactive immune systems, rather than stimulating them.

Glaxo is in phase III trials with a “potential” regulatory filing between 2021 and 2025.

This collaboration produced a single-digit (sub \$10 million) milestone payment in January 2015, with the promise of £64 million in potential milestones and royalties.

“This has the chance of becoming a real game-changer in the way auto-immune diseases are treated,” Mr Voigt says.

Mr Voigt adds that he was heartened that this program was not part of a recent review at Glaxo that saw the axing of 13 clinical and 20 preclinical programs.

In China, Prima’s partner Eddingpharm and its affiliate EOC Pharma are working on Chinese regulatory and clinical pathways.

Prima says: “as the legitimacy of LAG-3 as a therapeutic agent ... continues to garner industry acknowledgment, so does our engagement with potential partners which is becoming more intense”.

Dr Boreham’s diagnosis:

Prima is in a sound financial position, courtesy of a \$6.5 million placement to specialist US investors in June (Prima has been Nasdaq-listed since 2012 but this was the first US raising).

These punters were also issued warrants which, if fully exercised before the January 2023 expiry, would raise \$US4.9 million.

Prima lost \$9.3m in 2016-'17, but with a \$17 million cash balance there are enough bikkies in the tin to see out calendar 2018.

Prima and its buddies have more clinical irons in the fire than a gold rush era blacksmith, but with such a surfeit of activities there’s the risk of being unfocused.

Sceptics have questioned why Immutep’s owners were willing to sell for such a modest sum if the clinical prospects were so bright.

If only one clinical program succeeds, Lucy and her fellow holders may finally strike gold dust. But as with a polly on the hustings, there’s no such thing as a core promise in biotechland.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never been dubbed Mr Harbourside Mansion but is happy to become one.