



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Prescient Therapeutics

By **TIM BOREHAM**

ASX code: PTX

Share price: 13 cents

Market cap: \$27.5 million

Shares on issue: 211,508,374

Financials (March quarter)*: revenue nil, cash used \$282,000, cash on hand \$6.29 million, estimated current quarter cash outflows \$1.43 million

* During the quarter the company received a \$1.06 million R&D Tax Incentive

Chief executive officer: Steven Yatomi-Clarke

Board: Steven Engle (chairman), Steven Yatomi-Clarke, Paul Hopper, Dr James Campbell

Identifiable major shareholders: Australian Ethical Investments (12.96%), Regal Funds Management (8.78%), Retzos Executive Pty Ltd (Chris and Susie Retzos) (6.12%), Andrew Morrison Stewart (3.2%), Armada Trading (4.81%), Margaret Khoo (2.12%), One Managed Investment (2.89%) Wigtown Pty Ltd (2.61%).

Now's the time for a targeted oncology therapy company to be loud and proud, given Merck's \$502 million swoop on Viralytics - which is still the talk of the sector.

Not that investors are entirely uncritical about the cancer wonder drug theme.

On April 10, Prescient announced what looked like okay clinical results for its early-stage breast cancer drug trial, but investors sent the stock down by two cents, or 14 percent, to 12 cents.

“It baffles me when you produce encouraging data - albeit early stage - and the company is worth less on the other side (of the announcement),” says CEO Steven Yatomi-Clarke.

Bear in mind that the shares had rallied from six cents in early March in anticipation of the results.

Banker’s prescient move

Prescient evolved from oncology house Virax Holdings, which acquired the current portfolio with the acquisition of Aktivite Therapeutics in October 2014.

Virax paid \$300,000 cash and 234 million of its own shares at one cent (\$2.34 million), with 100 million shares up-front and the remainder subject to milestones.

Virax then undertook a one-for-20 share consolidation and changed its name to Prescient.

Current chief executive officer Steven Yatomi-Clarke succeeded Rob Crombie in February 2016.

Mr Yatomi-Clarke was corporate finance director at Paterson Securities. As a biotech specialist he was involved in a number of big-ticket deals in the sector, including Halcygen’s acquisition of the former Faulding operations (the precursor to Mayne Pharma).

Mr Yatomi-Clarke is a scientist by training with a Melbourne University honors degree in biochemistry and molecular biology, as well as a commerce degree.

He describes himself as an “acquired taste”, fitting the famous Jimmy Barnes descriptor of “a simple man with a heart of gold”.

“I worked with so many companies that I learnt how to do things and not to do things,” he says.

One example was dealing with regulators. “I saw companies getting defensive with the FDA and digging their heels in. That never ends well.”

He engineered Prescient’s last capital raising himself, “which annoyed a few brokers around town”.

Prescient shares DNA with Viralytics, in that Viralytics chair Paul Hopper is a Prescient director. Mr Hopper also chairs immuno-oncology play Imugene, which also enjoyed a share price romp after the Merck-Viralytics deal.

Pressing the right buttons

Prescient's lead drug PTX-200 inhibits the tumor survival pathway Akt, which is linked with breast and ovarian cancer and leukaemia.

A company presentation illustrates this mechanism of action with an on-off button. When the aberrant Akt is stuck 'on', the cancer cells are ordered to grow.

When it's 'off', they're not - and the cancer cells die.

It's actually more complex than that. Suffice to say, PTX-200 is touted as a novel mechanism-of-action that will inhibit Akt while being comparatively safer and better targeted than existing non-specific kinase inhibitors.

Prescient's second drug candidate is PTX-100, which has the ability to block the cancer growth enzyme geranylgeranyl transferase.

Yes, that's right. Yes, that's right.

It works in a similar switch mechanism to PTX-200, albeit on a different cancer 'button' - PTX-100 addresses the Ras and Rho mutations.

To date, \$US20 million has been sunk into developing the drugs by owners' past and present.

In the clinic

In the company's "most significant clinical milestone to date", Prescient reported the early-stage results of a PTX-200 breast cancer trial on April 10.

Overall, the US based trial treated 28 patients, focusing on women who did not display some or all of the receptors commonly found on cancer cells: oestrogen, progesterone and HER2-negative.

The patients had locally advanced or metastatic HER2-negative cancer and received a hit of both PTX-200 and paclitaxel (chemotherapy). Ten patients were evaluable for efficacy.

Of the five with the locally advanced disease, a 100 percent overall response rate was achieved with two showing a complete response (i.e. the cancer was banished). This is especially important as it's the focus of the current phase II study.

Of the 10 patients, five - or 50 percent - had an overall response rate, compared with the 25 percent the industry would expect from paclitaxel alone.

Mr Yatomi-Clarke said he was very pleased the best responses were in patients with the oestrogen-positive form of the disease, "which is especially difficult to treat and with poor expected outcomes from current chemotherapy regimens alone".

The trial (with 26 patients) is now in phase II, with five of the phase Ib patients participating.

If the overseers observe three partial or complete responses among the first 11 patients, the trial expands to another 15 patients.

The timing of this achievement can't be pinned down, because the desired response might be in the first or last patient treated.

The trial is at the New York-based Albert Einstein College of Medicine's Montefiore Medical Centre, and the Tampa, Florida-based H Lee Moffitt Cancer Centre.

Other events the punters will be awaiting are the results of earlier stage trials of PTX-200 for ovarian cancer and acute myeloid leukaemia (AML). PTX-200 is now envisaged as a combination drug to be used with the standard-of-care chemotherapy treatment.

This program is overseen by Prof Jeff Lancet of the Moffitt Centre. As well as having the best name in the medical game, he is a world-leading leukaemia expert.

The company expects initial results from ovarian cancer by the end of 2018 and AML results by around the middle of this year.

Wait! There's more ...

Let's not forget PTX-100, which in phase I trials was well-tolerated and achieved stable disease status for advanced solid tumors.

Now it's back to the clinic, but this time the company is targeting a range of cancers harboring mutations in cancer switches called Ras and Rho.

PTX100 inhibits the activation of Rho, Rac and Ral circuits in cancer cells, which are key pathways to blocking tumor growth.

The PTX-100 study will focus on Ras and Rho-A mutant malignancies, "including Rho-A mutant lymphomas".

Dr Boreham's diagnosis:

Prescient compares its approach to the Nasdaq-listed Loxo Oncology, which has followed a similar development path.

Loxo, which has two mid-stage candidates, recently entered a deal with Bayer involving \$US400 million of up-front payments and a total potential value of \$US1.55 billion.

With only phase II data, Loxo has applied to the FDA for investigational new drug status to treat a range of solid tumor patients.

“We will try to follow a similar development path,” Mr Yatomi- Clarke says.

He reckons the \$6 million is enough to last the company well into 2019.

But old banker that he is, he adds: “You don’t wait until the petrol tank is empty until you pull into the servo.”

Prescient shares may not have saluted on the occasion, but ultimately clinical data is the truth serum for any biotech.

In a year or so we’ll know whether Prescient should be worth Loxo’s \$US4 billion market cap - or somewhat south of that.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is just a working-class man trying hard to make a living.