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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Viralytics

By TIM BOREHAM

ASX code: VLA; **Market cap:** $256m; **Share price:** $1.06

Chief executive officer: Dr Malcolm McColl

Board: Paul Hopper (chairman), Peter Turvey, Dr Leonard Post, Dr McColl.

Financials for 2015-'16: revenue $513,000, loss of $9.06m (previously $4.25m); December quarter cash burn $3.78m; cash on hand $39.5m.

Major shareholders: BVF Partners (13.6%), Cormorant Global Healthcare (8.9%), Quest Asset Partners (7.5%), JCP Investment Partners (5%), Orbimed Advisors (5%).

Folk who believe winter sniffles have been a source of nothing but misery for human-kind have not cast their eyes over immunotherapy house Viralytics, which is pursuing a range of cancer indications with its proprietary Cavatak treatment, derived from the Coxsackie (common cold) virus.

Cavatak's mechanism of action is to target the receptors (called ICAM-1, seeing you asked) over-expressed in cancer tumors. Cavatak acts by directly killing tumor cells, as well as stimulating the body's own immune system to shrink other tumors. The virus can be delivered intravenously, or into the lesion itself.

Target indications include breast, lung, prostate, colorectal cancer and melanomas, a market estimated by Credit Suisse to be worth $US42 billion.

Viralytics, which has been listed for more than a decade, began its clinical work using Cavatak as a monotherapy to treat skin cancers, through the Calm, or Cavatak in late-stage melanoma, study. The melanoma skin cancer programs are the most advanced.

Cavatak evolved from the work of Prof Darren Shafren, associate professor of virology at the University of Newcastle and the company's chief scientific officer.

Viralytics' most advanced effort, the 57-patient phase IIb Calm study, showed an overall response rate of 28 percent, as well as a durable response rate of 21.1 percent six months after the advanced melanoma patients were treated.

Another mono-therapy program, the 16-patient, phase I systemic treatment of resistant metastatic disease, or Storm A, trial treated patients with melanoma, non-small-cell lung cancer, bladder and prostate cancer and has reported its results.

Part B of the Storm trial for advanced lung and bladder cancer has attracted big pharma Merck as a "collaborative partner", with Viralytics funding the programs but Merck providing know-how and (most importantly) access to its programmed cell death PD1 antibody checkpoint inhibitor Keytruda. The 80-patient study, also known by the Merck name of Keynote-200, is underway and the company expects results by the end of 2017.

A separate study called Canon, or Cavatak in non-muscular bladder cancer, has enrolled all 16 patients at the UK's Royal Surrey Hospital and has also reported results.

While the stand-alone treatments recorded initial success in reducing the size and spread of tumors, Viralytics has expanded its focus to a combination treatment with the extant "immune checkpoint inhibitor" drugs Yervoy (ipilimumab) and Keytruda (pembrolizumab), the drugs that saved property tycoon Ron Walker in their experimental phase.

Two key combination trials have targeted advanced metastatic melanomas.

In the Keytruda, 30-patient, phase Ib Capra, or Cavatak and pembrolizumab in advanced melanoma, trial, Cavatak achieved a 100 percent disease control rate among the first 10 patients. Of these, seven showed an objective response, that is, shrinking tumors, while three were stable. More updates are expected as patients are treated through this year.

The phase Ib Yervoy combination study, entitled the melanoma intra-tumoral Cavatak and Ipilimumab, or Mitci, trial, showed that half of the 18 patients recorded tumor mass reduction at day-106, while three showed a complete response. A further five patients showed stable disease at day-106, also with more updates expected as patients are treated through this year.

Viralytics has a phase Ib intravenous Cavatak in combination with an anti-PD-1 drug trial for melanoma in the planning stages, along with combination trials for other solid cancers.

The company describes the results as "preliminary but encouraging" bearing in mind the patients had failed previous treatments.

Dr McColl says the existing treatments have already moved the survival timeline. Five years ago, survival rates for advanced patients after five years would have been in the low single digits, rather than 20 percent at present.

Of course the challenge of combination therapy is to boost these survival rates further and ultimately render these cancers a chronic disease rather than a fatal condition.

“We are trying to get a much higher response rate in late-stage patients,” Dr McColl says.

With the ever-present danger of treatments attacking healthy tissues, another key aim of the Cavatak programs is to reduce the incidence of adverse events. Viralytics reports severe adverse events of six percent in its Cavatak-Yervoy patient cohort, compared with up to 55 percent for trials elsewhere (ipilimumab alone and other combination trials).

FINANCIALS:

Viralytics sits on cash of $40 million, by virtue of a $28 million capital raising and a $4 million share plan in early 2016. With a modest burn rate of $11 million last year (less a Federal grant of $3 million), Dr McColl says Viralytics should be able to fund its activities for the foreseeable future and management is keeping an open mind on whether to self-fund the more expensive pivotal (late stage) programs.

Dr McColl notes the potential to jump from the phase I/Ib stage (typically 20 to 30 patients) to phase III without the regulatory obstacles of yore.

“The Food and Drug Administration (the US regulator) says with the right data it will approve smaller studies,” Dr McColl says.

TIMETABLE:

Investors should look out for Storm data (metastatic bladder cancer) later this year.

If the results are pleasing, Viralytics might fund a single-arm pivotal study off its own bat. Otherwise it’s a case of following the global medical jamborees at which Viralytics is appearing, starting with the Leerink Global Healthcare Conference in New York next week. In political-speak, it always pays to rock up to these events with “announceables”.

INVESTMENT PROPOSITION:

While Viralytics is a one-drug play with Cavatak, the range of programs adds to both the potential of the story and the danger of investors simply being baffled. Arguably Viralytics has produced more data than any other ASX biotech, not that there’s anything wrong with that.

“It’s a pretty complicated story,” Dr McColl says.

A picture tells a thousand words. Viralytics presentations contain gruesome before-and-after shots of treated patients, which graphically highlight tumor shrinkage.

Just don't look at them before dinner.

DR BOREHAM'S VERDICT:

Arguably Viralytics current market valuation balances the multi-pronged potential with the reality the programs are in the early stages.

The company's register is replete with institutional backers, so the company should have few problems when the fund-raising fedora is next passed around.

Recent global immunotherapy deals imply a higher valuation. For instance, in September last year Boehringer Ingelheim entered a deal with the pre-clinical stage Vira Therapeutics in an options deal worth up to $US236 million.

Ultimately, Viralytics fortunes rest on a big-dollar big pharma partnership, or an outright sale of the company. The company's corporate strategy is to "license, partner or sell at a key value point".

In the meantime, don't forget to Slip Slop Slap.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Nor is he a licensed financial adviser.