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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Qbiotics Group

By TIM BOREHAM

Chief executive officer: Dr Victoria Gordon

Qbiotics is a public unlisted company

Shares on issue: 488,008,967; **Share price*:** $1.27; **Nominal valuation:** $619.8 million

***** Based on the average of the last 10 trades through the company's facility, between August 25, 2022 and September 20, 2022

Financials (12 months to June 2022): revenue $1.54 million (down 19%), government grants $6.38 million (up 8%), loss of $18 million (previously a $14.3 million loss), cash on hand $84 million (down 16%)

Board: Rick Holliday Smith (chair), Dr Victoria Gordon, Dr Paul Reddell (executive director), Andrew Denver, Dr Steve Ogbourne, Neville Mitchell, Dr Susan Foden, Nicholas Moore, Prof Bruce Robinson, Hamish Corlett (TDM representative)

Major shareholders: TDM Growth Partners 11.4%, Dr Gordon 6.73%, Dr Reddell 6.14%.

What Australian biotech is valued at more than $600 million and has an approved veterinary product, as well as an active human clinical program in oncology and wound healing?

Being unlisted, the Brisbane-based Qbiotics is unlikely to come to mind. But based on thin off-market trading the company is ascribed a nominal worth easily over half a billion bucks and boasts a retinue of big-name directors and shareholders.

Co-founded by research scientist Dr Victoria Gordon and husband and forest ecologist Dr Paul Reddell, Qbiotics is furthering key compounds based on biologic material from the Daintree rainforest (a.k.a. nature's pharmacy).

Having got a canine cancer treatment to market, Qbiotic's focus has returned to treating two-legged cancers including melanoma and the difficult-to-treat head and neck squamous cell carcinoma (HNSCC).

"There is good stuff happening [with the animal drug, Stelfonta] but the focus at the moment is our oncology human clinical trials," Dr Gordon says.

Four human trials are in progress (see below).

"Things are certainly moving forward pretty positively," Dr Gordon says. "Like everyone else, we have been hit by slow patient recruitment on our clinical trials but you just keep doing what you're doing."

The story to date

Both founders were employed by the Commonwealth Scientific and Industrial Research Organisation, but in 2000 Dr Gordon quit her day job to form Ecobiotics and the duo then formed Qbiotics - into which Ecobiotics was merged - in 2004.

Qbiotics' work revolves around a substance called tigilanol tiglate which Dr Gordon and Dr Reddell stumbled on when fossicking in rainforest in the Atherton Tablelands of Far North Queensland. They observed that animals spat out the seed of the blushwood tree - or Fontainea picrosperma to the Latin scholars among us - pointing to a non-toxic deterrent preventing the critters from eating and thus destroying the seed.

Using its Ecologic platform, Qbiotics isolated tigilanol tiglate - also known as EBC-46 - and tests for anti-cancer activity in animals proved safe and effective. The company is also developing EBC-1013 a semi-synthetic analogue of tigilanol tiglate for wound healing.

The compound was selected from more than 100 potential assets on the company's drug discovery platform, Eco Logic, after a long weeding-out process.

"We push our drugs to fail, because if you fail early, you fail cheaply," Dr Gordon says.

A talented lot

Dr Gordon has been a director of Biopharmaceuticals Australia, a member of the Queensland Government's Biotechnology Advisory Council and chair of the Australian Rainforest Foundation.

"My background is as a research scientist, but I really love the business side of the company," she says.

The Qbiotics board includes former ASX and Cochlear chair Rich Holiday-Smith and - more recently - Nicholas Moore, who ran Macquarie Bank for 10 years and knows something about following the money.

Prof Bruce Robinson chairs the National Health and Medical Research Council. Neville Mitchell was Cochlear's chief finance officer, while Andrew Denver is the former executive chair of Universal Biosensors.

Animal magic …

A new way of tackling cancer, tigilanol tiglate works largely through specific protein kinase C (PKC) activation.

Or as Dr Gordon explains: "It locally stimulates the immune system resulting in destruction of the tumor mass and the tumor's blood supply, followed by rapid healing of the site with minimal scarring."

Branded as Stelfonta, the substance was approved by the European Medicines Agency in May 2020, followed by the US Food and Drug Administration in November 2020 and the Australian Pesticides and Veterinary Medicines Authority in July 2021.

Stelfonta is indicated for all grades of canine mast cell tumors, the most common form of canine cancer. These days one in four dogs will die from cancer, partly because they are living longer.

Stelfonta is administered by injection directly into the tumor mass.

The current standard of care is surgery - but anaesthesia is dangerous for older dogs and brachycephalic breeds (short snouted ones such as bulldogs, boxers, pugs and shih tzus).

The May 2020 EMA approval was supported by a pivotal study of 123 hounds with mast cell tumors which account for one-fifth of all canine cancers.

Twenty-eight days after a single injection of the drug, 75 percent of the dogs had a complete response. The randomized and blinded trial involved an untreated control group that received rescue therapy after the 28 days. The trials were held at 11 clinics.

Stelfonta is distributed by the French group Virbac, on a profit-sharing basis.

Dulled by slow sales …

While 10,000 vials of Stelfonta have been sold to date, Dr Gordon admits sales have been "a little slower than forecast" and more education of veterinarians is needed.

"Virbac are doing a really good job in a tough environment," she says. "We launched the drug in the middle of Covid [in Germany].

“The drug uptake has been a little bit slower than we forecast but it definitely entails a paradigm shift, as an alternative for surgery.”

Dr Gordon is pleased by the repeat use, such as by a canine oncologist in the US who has treated more than 50 hounds over 12 months.

It certainly worked on one of the oncologist’s patients, an American cocker-spaniel named Treasure, who was bounding around 48 hours after treatment for a mast cell tumor between his toes.

Two-legged trials

In summary, Qbiotics has four human trials on the go - or rearing to go.

The trials follow “some very nice immunological systemic potential in our preclinical mouse studies, as well as a couple of abscopal effects in phase I”.

(The abscopal effect is when untreated tumors shrink alongside treated ones).

Two melanoma trials are taking place at multiple Australian hospitals, one of them a dose escalation rial (with pembrolizumab, marketed as Keytruda) and the other a monotherapy.

With the sites pretty much closed for 12 months during the pandemic, wrangling patients has been slow but recruitment has started.

Meanwhile, a phase II trial will start recruiting patients with head and neck squamous cell carcinoma in several UK sites, overseen by a ‘key opinion leader’. Australian sites are also planned, with a total up to eight to be opened by the end of 2023.

The company recently obtained investigation new drug approval from the US Food and Drug Administration to carry out a 10-patient phase II soft tissue sarcoma trial and “we will be recruiting patients for that trial hopefully by the end of the year.”

Dr Gordon says the rare soft cell sarcoma is interesting because there are 70 different tumor types: “If we can get a general response that would be significant.”

She says while the studies target externally accessible tumors, the drug has the potential to be internally injected for breast and prostate cancers.

“It’s not a fussy drug, it’s easy to use and has stability on the bench for a week or more,” she says. “It usually is administered via a single injection with no general anaesthetic required, which is beneficial for compromised or aged patients.”

Dr Gordon adds the company will look to find a partner at the phase II stage: “there’s a lot of potential with this drug and it deserves to get into the hands of a company with significant capabilities.”

Finances and performance

Qbiotics generated $1.54 million of revenue in the year to June 30, 2022, 19 percent lower than the previous year. Of this, revenue from the veterinary drug contributed just over $915,000.

Dr Gordon says this income “is a poor reflection of the potential of the drug” and expects sales to improve post-pandemic.

As a guide to this potential, Qbiotics initially forecast a $US200 million to $US300 million ($A320 million to $A480 million) total addressable market for Stelfonta, now whittled back to a more conservative $US100 million.

In early 2021, the company raised a hefty $85 million, with investment firm TDM Growth Partners accounting for $50 million (existing holders took up the rest).

As a result, TDM co-founder Hamish Corlett joined the Qbiotics board.

At the end of August 2022, Qbiotics had $84 million in the bank, including long-term investments. “At the moment our burn rate is sitting at around $7 million [a quarter], so we are fairly comfortable,” Dr Gordon says.

The company cites accumulated losses of $80 million, which in effect is the sunk cost of developing the drugs to date.

It’s time to heal all wounds

While Qbiotics is focused on oncology, Dr Gordon is just as excited about a variant product (a semi-synthetic analogue) being developed for wound healing.

“It’s a drug rather than a device, which is rare in the wound healing space,” she says.

An easy-to-use gel, the compound has anti-microbial effects and promotes infill healing to prevent scarring and wound closure.

The company has been working with tissue repair specialists at Cardiff University for the last eight years.

Dr Gordon says the UK regulator, the Medicines and Health Products Regulatory Agency, supports the proposed structure of a clinical trial, which is likely to target venous ulcers and is due to kick off by October 2023.

“There’s been a lot of excitement among key opinion leaders because of its mode of action,” she says.

The disadvantage is that drugs are harder to have approved than devices, but regulators have been positive at the early stage.

Dr Boreham's diagnosis:

Given that even the most loyal investors desire a so-called liquidity event, the question on the lips of Qbiotics 2,500 shareholders is when - rather than if - the company plans to list (presumably on the ASX).

"We have been planning [a listing] for a long time," Dr Gordon says. "Our corporate finances and our governance is very good and the company is very well managed."

But she says a listing is likely to occur after - rather than before - positive human clinical results to get the best valuation possible.

"I don't want to just cope when we list, I want to flourish," she says.

Dr Gordon stresses while the revenue from the veterinary side is only trickling through, it will improve. After all, Treasure the pooch's miracle recovery should attest to that.

Ultimately, the make-or-break event for the company is getting a blockbuster human drug to market. As with next Tuesday's crowd at Flemington, it's a case of being off to the races for Qbiotic holders at that juncture.

Disclosure: Dr Boreham is not a qualified medical practitioner or veterinarian and does not possess a doctorate of any sort. He is not Latin scholar but knows a Fontainea picrosperma from an in vino veritas, whenever he meets them. Caveat emptor.