



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Qbiotics Group

By TIM BOREHAM

Chief executive officer: Stephen Doyle

Qbiotics is a public unlisted company

Shares on issue: 489,026,611

Financials (half year to December 31, 2024): revenue \$1.16 million (up 6%), government grants \$3.89 million (-4%), loss of \$9.3 million (previously an \$8.5 million loss), cash on hand \$39.2 million (down 15%).

Board: Mark Fladrich (chair), Mr Doyle, Dr Victoria Gordon (co-founder), Dr Paul Reddell (co-founder), David Phillips, Sergio Duchini

Major shareholders: TDM Growth Partners 11%, founders and staff 13%, other Top-20 shareholders 24%, remaining shareholders 52%

Like other IPO candidates – and the list is growing - private oncology drug developer Qbiotics has been closely watching the trajectory of Virgin Australia since the airlines June 24 ASX listing.

The biggest float since fast food chain Guzman y Gomez spiced up things in June last year, Virgin's initial public offer (IPO) has been seen as a barometer of broader investor appetite for new offerings.

With Virgin shares holding nicely at cruising altitude, is it time for the Brisbane-based Qbiotics to debut?

Qbiotics chief Stephen Doyle says IPO timing has never been right in the past, but the company now is positioned to crawl through the window of opportunity when it opens.

In March the company appointed Jeffries and Bell Potter as joint lead managers for the putative float, and it is getting its financial reporting into shape.

“We have done the due diligence and prospectus drafting ... all the things you need to do for an IPO,” Mr Doyle says.

“At the end of the day it’s picking the right time with the right catalysts to create value for shareholders.”

Tapping nature’s pharmacy

The company may have found such a catalyst, having last month reported encouraging results from its phase II soft tissue sarcoma (STS) trial.

The study road tests Qbiotics tigilanol tiglate (EBC-46), which derived from the depths of the Daintree rainforest.

The company says tigilanol tiglate has a “multi-factorial mode of action”, including activating the protein kinase C.

This leads to the disruption of the tumor’s blood supply, while also stimulating a local inflammatory response.

Separate from this, tigilanol tiglate can directly kill cancer cells within the tumor, in a way that promotes the development of anti-tumor immunity.

This is like how a vaccine works.

Qbiotics has phase II programs for both soft tissue sarcoma and head and neck cancers (HNCs).

It also has less advanced programs in venous leg ulcers and anti-microbial and anti-inflammatory applications.

Dogged effort wins canine approval

Qbiotics has an approved product, Stelfonta, to treat canine mast cell tumors.

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). Stelfonta is administered by injection directly into the tumor mass.

The European Medicines Agency approved Stelfonta in January 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 distributed by the French group Virbac, which is responsible for all sales and marketing, while Qbiotics provides the finished product at a suitable margin.

Mr Doyle says the veterinary drug showed Qbiotics could take a product all the way from discovery to commercialization.

“It was also a derisking strategy,” he says. “The canine is a good surrogate for the human setting and that has been the case. We have some good safety and efficacy data in well over 20,000 dogs”.

Stelfonta recently won a label expansion in the UK, for use in resectable mast tumors (not just inoperable ones).

The story to date

Qbiotics was co-founded by research scientist Dr Victoria Gordon and husband and forest ecologist Dr Paul Reddell.

Both founders were employed by the Commonwealth Scientific and Industrial Research Organisation, but in 2000 Dr Gordon busted out to form Ecobiotics.

The duo then formed Qbiotics - into which Ecobiotics was merged - in 2017.

The pair stumbled on tigilanol tiglate when fossicking in rainforest in the Atherton Tablelands of Far North Queensland.

They observed that animals spat out the seed of the blushwood tree, pointing to a non-toxic deterrent preventing the critters from eating and thus destroying the seed.

Qbiotics isolated tigilanol tiglate and tests for anti-cancer activity in animals proved safe and effective.

Mr Doyle was appointed in early September 2024 after Dr Gordon stepped down, but she remains on the board.

At the time, Mark Fladrich and David Phillips were appointed, while Andrew Denver and Prof Bruce Robinson stepped down.

The company's chair, Dr Susan Foden died suddenly in early November and Mr Fladrich assumed the chair role.

The board previously included former ASX and Cochlear chair Roderic Holliday-Smith, Cochlear chief financial officer Neville Mitchell and erstwhile Macquarie Bank CEO Nicholas Moore.

Taking the low road and the high road

A Scottish pharmacist, Mr Doyle has a long history with big pharma companies in medical and commercial roles.

Since peregrinating to Australia at the end of 1999 on a working holiday visa, Doyle has held roles with Janssen, Novartis, Sanofi and Boehringer Ingelheim.

He had lengthy stints in Paris, Singapore and Shanghai, before being poached by the smaller Aslan Pharmaceuticals (based in the Lion City).

"I liked the idea of roll up your sleeves and multi-tasking, whereas with big pharma you tend to get pigeon-holed," he said.

Mr Doyle joined Qbiotics partly because he liked the idea of returning to Australia, notably Brisbane, but also because of the buzz of developing a drug.

"The risk of biotech is quite exciting," he says.

"It's not for everyone. If you want a nice stable job ... get a job at Pfizer."

Soft tissue sarcoma

Soft tissue sarcoma (STS) is a rare cancer that generally forms as a painless tumor in any bodily soft tissue.

The company says there were 128,000 new cases of STS globally in 2023, with the incidence growing at about half a percent per year.

The US Food and Drug Administration has granted tigilanol tiglate orphan drug status for this indication.

Conducted at New York's Memorial Sloan Kettering Cancer Centre, stage one of the phase IIa trial covered 10 evaluable patients with advanced STS.

The study achieved an objective response rate of 80 percent in injected tumors, with eight patients having a complete ablation or partial ablation (reduction of 30 percent or more).

Of the injected tumors, 22 out of 27 (81 percent) showed complete or partial ablation (14 complete).

"None of the 14 completely ablated tumors recurred at six months, indicating tigilanol tiglate may provide durable responses," the company says.

The trial moves to an expanded second stage, with another 40 patients targeted.

Mr Doyle says there are around 80 to 120 STS sub types, but the company intends to narrow its work to the most common varieties.

Head and neck cancers (HNC)

Qbiotics currently is recruiting in Australia and UK for the HNC phase II trial.

As with the STS trial, it is single-arm and open label.

An earlier 19-patient phase I/II trial met safety and tolerability goals.

Head and neck cancers are a portfolio of cancers afflicting the mouth, nose, throat, voice box, sinuses, and salivary glands.

Mr Doyle says HNCs are challenging in at least two ways. For a start, they occur close to vital organs and vessels.

Secondly, patients tend to be from lower socio-economic areas. For instance, mouth cancer is quite prevalent in India and may result from chewing betel nut.

Smoking and chewing tobacco and alcohol are key risk factors with mouth and voice box cancers.

Oro-pharyngeal cancers are linked to the human papillomavirus.

The company hopes to release top-line data later this year.

Here, there and everywhere ...

Mr Doyle says tigilanol tiglate is an “interesting molecule” because it has multiple modes of action. This includes some evidence of an abscopal effect, over and above the drug’s direct effect on the tumor.

The abscopal effect is when localized cancer therapies lead to the shrinkage or even disappearance of tumors elsewhere in the body.

Not surprisingly, the immune system is thought to transmit the tumor kill signals.

In an ‘off study’ observation the abscopal effect was seen in a melanoma patient, in an earlier phase I ‘all comers’ study.

(The company carried out two melanoma studies, one of them a dose-escalation effort in combo with Keytruda and the other a monotherapy).

The company is carrying out exploratory work on the abscopal effect in the STS and HNC programs and hopes to present data at an upcoming congress of learned peers.

In the background, the company is also undertaking a dose escalation and safety study for venous leg ulcers, which remain stubbornly hard to treat. A semi-synthetic variant, this one would be a drug rather than a device, which would be rare in wound healing.

Finances and performance:

Qbiotics' unlisted status hasn't prevented the company from raising large wads of money: \$194 million since inception, plus \$60 million of tax incentives and government grants. 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).

At the end of December 2024, the company had cash of \$39 million.

"We have enough money to deliver on our outlined programs, including part two of the STS trial and a venous leg ulcer study," Mr Doyle says.

In the December half year, the company generated \$1.16 million from Stelfonta sales, which "continued to be lower than expected".

With its level of disclosure, Qbiotics' annual report looks more like the work of a listed company. With no listed mechanism - or not yet anyway - buyers and sellers can trade separately via www.wholesaleinvestor.com.

Dr Boreham's diagnosis:

Mr Doyle says Qbiotics' strategy has been to generate data in multiple tumors, including melanoma, to broaden the company's commercial appeal.

"For us it is about creating proof of concept and evidence in multiple solid tumor types, to make us attractive for partnering. "Our sweet spot is phase II or IIb, but we need to find a big partner ... with the necessary infrastructure and resources to run multiple registration studies targeting multiple solid tumor types."

He says Qbiotics is not yet at the point of having to hone its indications of interest.

"We are small nimble and get to wear multiple hats, but ultimately we are limited by resources."

In its 25th year, Qbiotics offers enough goings-on to maintain the interest of the company's circa 2,600 shareholders ahead of the listing.

For the record, Grandview Research values the STS market at \$US1.26 billion in 2023 and reckons the HNC sector will be worth \$US5.2 billion by 2030. The vet market is estimated at \$US100 million. That's decent enough, but a morsel compared to the human oncology opportunities.

Disclosure: Dr Boreham is not a qualified medical practitioner or veterinarian and does not possess a doctorate of any sort. Nor does Dr Google, but that doesn't stop him from being the most trusted doctor in town.

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