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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: TBG Diagnostics

(Formerly Progen Pharmaceuticals)

By TIM BOREHAM

ASX code: TDL

Share price: 27 cents (trading suspended)

Market cap: $58.74 million

Shares on issue: 217,587,289

Executive chairman: Indrajit Solomon (Jitto) Arulampalam

Board: Jitto Arulampalam, Dr Stanley Chang, Emily Lee, CK Wang

Financials (calendar 2019 year): Revenue (continuing operations) $3.3 million (up 6%), net profit $620,137 (previously $4.4 million loss), loss on continuing operations $11.2 million (previously $2.53 million deficit), cash of $5.2m (down 8%).

Major shareholders: Medigen Biotechnology Corp 48.68%, Eternal Materials Co 18.48%.

As could be expected, the molecular diagnostics house's announcement of European approval of its Chinese investee company's Covid-19 test was greeted with a powerful share rally.

The trouble is, some investors appear to have developed psychic powers and weighed in before the European regulator's approval was announced to the market on Wednesday March 18.

TBG Diagnostics stock was suspended the previous day, but not before surging from 2.6 cents on February 26 to 27 cents - a rise of 938 percent.

As they say, the early bird catches the worm! If only these seers had had the foresight to predict the Covid-19 plague itself and helped us all avoid it.

TBG Diagnostics shares are now frozen in time (suspended) as the ASX makes “further enquiries” about the heavy volumes and irregular trading leading up to the announcement.

In a reply to an ASX query, management explained that Taiwan based director Dr Stanley Chang became aware of the assent informally on Saturday March 14.

This was via the investee company TBG Biotech Xiamen, which is 46.65 percent owned by TBG Diagnostics.

TBG Diagnostics argues the delay ensued because management needed to sight the official Conformité Européenne (CE) mark paperwork and that it reasonably believed the news would be confidential until then.

“We expected (the announcement) would give us good exposure but being suspended is not a good look,” rues executive chairman Jitto Arulampalam.

TBG who?

While the disclosure probe is an unwelcome distraction, at least the European approval highlights the existence of one of the bourse’s lower key biotechs.

Indeed, one figure in the molecular diagnostics sector told your columnist he had never heard of the company! But possibly he might recall a long brawl over cash in 2008 (see history, below).

TBG Diagnostics is already revenue generative and profit making, with approved products in Taiwan and China via TBG Xiamen and its fully-owned subsidiary TBG Taiwan.

Ready to go

The European approval relates to TBG Xiamen’s nucleic acid diagnostics kit, which uses real time polymerase chain reaction (PCR) technology to detect distinctive genetic segments of the Covid-19 virus.

More specifically, the test uses RNA (ribonucleic acid) to detect the RDRP, N and E genes of the virulent lurgy.

The in-vitro diagnostic (IVD) kit will be available for “immediate validation and purchase”.

Mr Arulampalam said TBG Xiamen had the advantage of working on 'flu diagnostics, with these efforts pivoting to the coronavirus as soon as the bug emerged in Wuhan province in November.

"The result was much better than expected," he said.

TBG Xiamen is now preparing to ship its first batch of 20,000 kits to Europe this week, with a vaunted selling price of $US15-25 ($A20-30) per test.

"It's now a question of how quickly we can scale up and manufacture the product in larger batches," he said.

TBG Xiamen has also received a "substantial order" from the US and was lodging a fast-track application with the US Food and Drug Administration.

"We hope to get into the US, given it's the country likely to be at the epicentre of it all," Mr Arulampalam said. "It's clear that more testing needs to be done quickly."

The company is also eyeing local Therapeutic Goods Administration approval.

Tracking Covid-19's genetic footprint

Initially focused on the in-vitro fertilization market, TBG markets numerous products and services from its certified core facility at Xiamen, a port city on the southeast coast in Fujian province.

Clients include hospitals, independent reference labs, blood centres and bone marrow registries. The purpose of the tests includes detecting infectious diseases, viral load testing and genotyping (used to detect a person's genetic variants).

For the boffins, the products include Exprobe (typing kits based on polymerase chain reaction technology) and HL Assure (human leukocyte antigen genotyping based on sequence-based typing). With the look and size of an air conditioner, the Q6000 PCR instrument will be the basis of a fully automated system in development.

Pay attention - you will be tested

Older - and of course venerable - readers will remember TBG Diagnostics as Progen Pharmaceuticals, the antecedent firm that listed in 1990.

Progen eventually came a cropper when it cancelled its seminal liver cancer trial, having raised a total of $150 million.

To cut a long and sometimes litigious story short, the current technology was vended into the group in 2016 via Taiwanese major shareholder Medigen, which had earlier acquired Texas Biogene (yep - TBG).

Around that time Progen changed its name to TBG Diagnostics.

In 2014, the company founded TBG Xiamen to address the Chinese government's requirements for foreign entities carrying out a genetic testing business.

In 2019, TBG Xiamen acquired Zhangsha Zhang Ye Medical Laboratory Corps, which provides medical lab testing services in Chairman Mao's old stamping ground of Hunan.

In the process, TBG Diagnostics' stake in TBG Xiamen was reduced to 46.65 per cent. The deal also involved a private equity firm injecting $2.25 million into TBG Xiamen.

Put in context, all the coronavirus testing action is taking place in Zhang Ye's certified lab.

In 2016, TBG Diagnostics' contract manufacturing arm, Pharmasynth, was acquired in a management-led buyout and renamed Luina Bio Pty Ltd. Luina continues Covid-19 related activity as well (see below).

In the same year, TBG sold its PG500 assets - in effect Progen's old oncology business - to the Brisbane based Zucero Therapeutics for $6 million in a cash and scrip deal.

Financials and performance

A key point is that the Covid-19 test activity is under the auspices of TBG Xiamen, not TBG Diagnostics.

Hence, TBG Diagnostics investors benefit not so much from direct revenues, but the value of TBG Biotechnology on its books ($3.14 million as of the end of December).

TBG Diagnostics revenues currently derive from TBG Taiwan, which is responsible for Asian sales outside of China.

TBG Xiamen serves as the company's sales distributor in mainland China (except Hong Kong and Macau) and is the only provider of sequence-based testing products approved by the China Food and Drug Administration.

Of the $3.34 million of revenue in 2019, 81 percent derived from products - mainly the sequence-based typing and sequence-based primer products.

A further eight percent of revenue was derived from technical services.

TBG Diagnostics reported an operating profit of $712,000 a sharp turnaround on the $3.5 million deficit in 2018.

But the number is confounded by a $2.85 million share of net loss of associates, a $6.38 million impairment loss and an $11.8 million credit mainly relating to the TBG Xiamen transaction.

Also clouding the picture is a $5.99 million gain from deferred settlement of the PG500 deal.

Meanwhile ...

The Brisbane-based Luina Bio has made it clear that it remains open for business during the pandemic.

“If you are working on a drug, a vaccine or a diagnostic to help battle Coronavirus, please contact us now for a fast consultation to see how we can work together for fast response to scale up and manufacturing.”

One such venture is a tie-up with Griffith University’s Centre for Cell Factories and Polymers, to marry Luina’s contract manufacturing expertise with the learning institution’s expertise in vaccine platforms.

Griffith has developed a rapid response vaccine platform technology that allows for low cost, large scale manufacturing of new pilot vaccine candidates ready for pre-clinical and clinical testing against an emerging viral threat.

Sounds topical, but can’t quite pin down why ….

Luina chief executive officer Les Tillack told Biotech Daily that with optimal conditions the vaccine candidate could be ready for human clinical trials in six to 12 months.

Mr Tillack said that the importance of the Griffith University-Luina process was that it could produce the vaccine “quickly and at a fraction of the cost of normal vaccines”.

Meanwhile, Zucero reckons its immune-oncology programs might also be relevant in the fight against Covid-19.

Dr Boreham’s diagnosis:

Just to show how much has changed in a short space of time, stock analysis site Simply Wall Street had this to say about TBG Diagnostics in early December 2019, when the shares traded around four cents.

“We don’t think TBG Diagnostics’ revenue of $3.42 million is enough to establish significant demand,” the site said. “So, it seems shareholders are too busy dreaming about the progress to come than dwelling on the current (lack of) revenue. For example, they may be hoping that TBG Diagnostics comes up with a great new product, before it runs out of money.”

These hopes have now been satiated, big time.

TBG's test joins a growing array of Covid-19 assays, ranging from fairly basic swabs to the more accurate nucleic acid testing.

"Our scientists are telling us that even though a swab test is negative it can turn out to be positive later, whereas [polymerase chain reaction] results are very accurate," Mr Arulampalam said.

"Hence the larger labs and path organizations are preferring PCR machines and our testing is built on that methodology."

In our humble view, TBG's imperative is to surf the Covid-19 potential while the bug remains an epidemic and before the market is swamped with various other tests.

But with the European paperwork in its back pocket, TBG has a head start.

TBG is also not just about Covid-19 assays. As of December, TBG had 24 products in development, with six in clinical trial or development stage for transfusion, immunity and infectious diseases.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort – or any psychic abilities beyond predicting the end of daylight savings this weekend.