Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

# Dr Boreham's Crucible: Sars-Cov-2 Tests

**By TIM BOREHAM**

**Ellume:** public unlisted

**Anteotech (ADO):** share price 26.5 cents, market cap $517 million, revenue (12 months to June 30, 2021) $2.4 million, up 90 percent, one year share gain 243 percent, movement since January 3, 2020 - 54 percent

**Genetic Signatures (GSS):** share price $1.505, market cap $215 million, revenue (12 months to June 30, 2021) $28.3 million, up 150 percent, one year share loss -22percent, share movement since January 3, 2020 - up 57 percent

**Atomo Diagnostics (AT1):** share price 29 cents, market cap $164 million, revenue (12 months to June 30, 2021) $6.7 million, up 25 percent, one year share loss -2.7percent, share movement since listing on April 16, 2020 – 75 percent

**Lumos Diagnostics (LDX):** share price 96 cents, market cap $144 million, revenue (12 months to June 30, 2021) $25 million, share loss since July 5, 2021 listing -23 percent

**Rhinomed (RNO):** share price 36 cents, market cap $91 million, revenue (12 months to June 30, 2021) $3.9 million, up nine percent, one year share price gain - 157 percent, share movement since January 3, 2020 – 70 percent

**TBG Diagnostics (TDL):** delisted (see below).

Despite the "grave risk to public health" posed by wrongly administering or reading point-of-care Sars-Cov-2* tests, such rapid assays are likely to become the norm as New South Wales and Victoria join The Great Reopening.

* Severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) is the virus that causes Covid-19. For simplicity we are calling all these Sars-Cov-2 tests Covid tests.

Sooner, rather than later, the local Therapeutic Goods Administration will decide on whether to allow rapid Covid self-administered tests that can be used at home (or elsewhere) without the involvement of a healthcare specialist.

We can safely assume a positive decision, given that Federal Health Minister Greg Hunt has flagged the regulator's assent "in coming months, if not weeks".

The TGA has already approved around 30 rapid antigen tests, but medicos are required to interpret the results.

Assent also seems inevitable because rapid tests are already approved in other key jurisdictions including US and Europe. Aldi sells off the shelf tests in its German stores (they sell for 25 Euros, or $A39 for a pack of five if you really want to know).

Early on in the Covid crisis, ASX-listed healthcare diagnostics companies were quick to jump on the rapid-testing bandwagon. Some have succeeded, some are kind of getting there and others have fallen off the rolling conveyance with a thud.

This week, Lumos Diagnostics had a setback when the US Food and Drug Administration (FDA) "deprioritized" the company's application for approval of emergency use of its Covid test.

Does that mean the corona-crisis is over?

**Explaining the tests**

The gold standard is the polymerase chain reaction (PCR) test, which involves queuing up for the 'brain stab' swab to winkle out mucus samples from the back of the nose.

The test goes to the lab and the quarantining subject has to wait to be advised of the result (turnaround times vary from hours to days).

But as vaccination rates creep up and folk emerge from "under the doona" (Tr: duvet, eiderdown) there's going to be a greater, ongoing emphasis on the easy but less reliable rapid tests.

These assays can be molecular or antigen based. The former detects viral proteins in the viral DNA and the latter detect antigens expressed by the body during acute infection.

A rapid molecular test is quicker than PCR but "a lot slower" than antigen.

Other serological (blood assay) tests look for tell-tale antibodies in the claret, but these biomarkers can take two weeks to be present post infection, and that tells you about disease, not the virus.

The rapid antigen tests are considered good for positives, but not so good for false negatives.

The TGA notes that self-tests are most accurate when used on a symptomatic person within the first few days of showing symptoms when the viral load is highest, “although their accuracy invariably has been shown to be lower than that of the PCR tests”.

The regulator is not a big rap for serologic (antibody detection) tests, given they provide only a retrospective diagnosis.

“It is expected that Covid-19 rapid antibody self-tests will continue to remain prohibited from supply in Australia.”

**Ellume**

Ellume is arguably the most advanced of the coronavirus detecting companies, with its rapid tests approved by the US Food and Drug Administration for emergency use. Unlike some of the other tests Ellume is not approved by the Australian Therapeutic Goods Administration, yet.

(Currently Federal Government law allows point-of-care antigen testing by health professionals, but not home testing.)

Ellume also has $300 million from the US Government to support production, not to mention deals done with two major airlines to test returning Americans, as well as distribution through US pharmacies.

As a public unlisted company, we don’t have access to Ellume’s historical financial data but the company said in February that it was on-track to procure about 200,000 Ellume Home Test Kits a day, which would sell for around $50 each.

**Anteotech**

Anteotech’s tests are lateral flow immunoassays, which are simple devices aimed at detecting a pathogen in a liquid sample, without the need for costly lab equipment.

In other words, it’s a rapid antigen blood test showing whether the user has the virus.

The test consists of a small desktop reader, into which the cassette (containing the patient sample) fits. A result is available within 15 minutes.

In March 2020, Anteo won Conformité Européenne (CE) mark approval for its tests, which the company claims are more reliable than rival assays. Yesterday, the company filed its application to the local TGA.

The tests are based on the highly sensitive fluorescent element, Europium, which lights up the antigens when subject to ultra violet light. Anteotech claims 97.3 percent sensitivity (correct positive results) and 99.6 percent specificity (correct negative results).

Pertinently, Anteo has already been supplying raw material for its unlisted Brisbane-based peer, Ellume, which is rolling out a home-based test.

Anteo's further plans lie in rolling out a saliva-based test that combines Covid-19, influenza A and influenza B testing.

(And in something completely different - the company is also pursuing a research program to improve the efficacy of lithium-ion batteries, which doesn't have much to do with Covid but could power some of the tests, we suppose.)

Anteo enjoyed a significant ramp-up in profile after Ellume's test was approved in the US.

Anteo posted sales of $2.41 million in the year to June 30, 2021, up 90 percent but lost $6.2 million.

Anteo's share performance has also been lacklustre: they peaked at 50 cents in late April, but now change hands for 29 cents, ascribing a $580 million market capitalization.

## Genetic Signatures

With a portfolio of PCR-based tests for indications such as respiratory, gastro-enteric strains, flavivirus/alphavirus, antibiotic resistant bugs and sexually transmitted infections, Genetic Signatures is far from a one-trick pony.

But having moved swiftly to get its molecular-based rapid Covid test approved last March, the company's respiratory tests have become a more important part of the undersized equine repertoire.

Sold under the Easyscreen banner, Genetic Signatures' tests were developed (and made) in Australia and can be sold in more than 30 European countries.

Approved in Europe and locally in March last year, the Covid tests are able to detect whether a patient has the affliction, but its multiplex test can detect a range of respiratory illnesses - such as rhinovirus, influenza A and B, and the laboratory reporting the result with a throughput of 188 samples in about four hours, per instrument.

Genetic Signatures chalked up sales revenue of $28.3 million in the year to June 30, 2021, 150 percent higher. The company also managed a $1.75 million profit compared to the previous $2.08 million loss. June quarter revenues climbed 27 percent to $5.4 million.

## Atomo Diagnostics

Luckily, Atomo already had a rapid blood-based diagnostic device for HIV - the only self-administered HIV assay approved by the TGA. Could the company's boffins tweak it into a Covid test? You betcha!

Atomo's business model involves providing the device to other test manufacturers in the US and Europe. Before you could say cytokine storm, the tests were being shipped to Europe under a 'white label' arrangement with French diagnostics house NG Biotech SAS.

The test can also be used for bacterial-versus-viral and pregnancy tests, with malaria, hepatitis C and Ebola tests also being targeted.

The tests are either a finished product in a nice package, or a naked device to which original equipment manufacturers can add their own test strip.

The tests take three steps, with a result in 15 minutes. While the pin-prick procedure requires more exposure to the virus than swab-based molecular lab-based tests, they can also test for antibodies after the symptoms and the virus have disappeared (or in asymptomatic patients).

Atomo reported revenue of $6.7 million in the year to June 30, 2021, 25 percent higher. Of this turnover, the Covid tests accounted for $3.68 million (55 percent) from the sale of 1.1 million units. Atomo lost $4.8 million on an underlying basis.

**Lumos Diagnostics**

The FDA on Wednesday said it had “ceased review” of Lumos’s rapid antigen test, Covidx, for emergency use, sending the shares down 12 percent.

Lumos remains in active dialogue with the regulator and is preparing additional data to support a fresh application, as you do. The test is already approved in Europe.

Lumos listed on July 5 this year, having raised a chunky $63 million.

The company’s flagship product is not Covidx but Febridx, a finger-prick blood test that can distinguish between bacterial and viral infections (such as Covid) within 10 minutes.

Lumos is also developing Viradx “which simultaneously tests for Covid-19 and influenza and has the potential to satisfy an even greater public health need”.

As extension products of Febridx, the company is developing Uridx for urinary tract infections and Sepsidx (for the often-fatal blood infection sepsis).

Of Lumos’s revenue of $25 million in the 2020-’21 year, $22.7 million derived from commercial services (white-label assay and digital reader development and manufacturing for other parties). Lumos also posted a $14.5 million loss, but one has to break a few eggs to make an omelette.

**Rhinomed**

Honourable mention goes to the nasal appendage specialist, which hasn’t devised a Covid test per se, but has come up with a more comfortable and faster way of deriving a sample.

The Rhinoswabs are low-tech, plastic clip-like devices that are inserted into the nostrils and collect the requisite snotty stuff from both nostrils.

Doherty Institute testing found “the eluted volume from Rhinoswab was found to be comparable to the commercially available [swab] when artificially dipped into a neat saliva solution and spiked with inactivated Sars-Cov-2 at both high and low virus burdens”.

The Rhinoswabs works with existing PCR pathology test flows, but are also very relevant for the home testing market. The New South Wales and Victorian health departments have ordered one million swabs each.

As Rhinomed notes, two billion tests have been carried out in the last 18 months, 26 million in Australia. Yep, that’s one for every man, woman and child.

Management says the contract terms are confidential but confides the Victorian deal equated to 35 to 40 percent of its $3.9 million revenue in the year to June 2021 (up nine percent). Okay, so let’s say at the midpoint it’s worth $1.56 million - and then double that for the New South Wales contract if Gladys isn’t getting a better deal than Dan.

**TBG Diagnostics**

TBG appeared to have its ducks in a row last year, with a molecular test that won European approval via Chinese affiliate TBG Xiamen.

The neatly aligned canards now look more disorganized.

In April 2020, TBG Xiamen was preparing to ship its first batch of 20,000 kits to Europe, with a vaunted selling price of $US15-25 ($A20-30) per test. TBG Xiamen also received a “substantial order” from the US and was lodging a fast-track application with the US Food and Drug Administration.

TBG Diagnostics already had approved non Covid products in Taiwan and China via TBG Xiamen and its fully-owned subsidiary TBG Taiwan.

But last month, TBG shares were removed from the ASX boards because of unpaid listing fees. Come to think of it, TBG shares have been suspended since March last year, relating to claims regarding both a Sars-Cov-2 and a Covid-19 test, so investors aren’t missing much.

**Dr Boreham’s diagnosis:**

Unless your diligent columnist is missing something – and he probably is – there’s a fair inconsistency between the valuations of the Covid testing aspirants.

Genetic Signatures has way more revenue than Anteotech and even managed a modest profit. Yet it’s worth less than half of Anteotech, which appears to enjoy a generous valuation ascribed to the boffin-y lithium-ion battery stuff.

Lumos generates similar revenue to Genetic Signatures, albeit unprofitably, but is worth two-thirds less.

In the words of Anteotech CEO Derek Thomson: “Despite slowly increasing vaccination rates, the global market is still large and the demand for rapid testing remains very strong.

“The market is however very competitive, with a wide range of tests available … with a wide range of performance characteristics.”

And we’ll leave the final health warning to the TGA:

“The misinterpretations of serology-based and rapid antigen point-of-care test results present a grave risk to public health and could result in serious illness and death of the patient and other persons that the patient comes in contact with.”

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. If taken too seriously, his musings present a grave risk to public health and could result in serious illness and death of the reader and other persons* with whom *the reader comes in contact - because we are, after all, grammarians.***