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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: LBT Innovations

By TIM BOREHAM

ASX code: LBT

Share price: 12.5 cents; **Shares on issue:** 288,742,895; **Market cap:** $36.1 million

Chief executive officer: Brent Barnes

Board: Kate Costello (chair), Brenton Barnes, Dr Caroline Popper, Simon Arkell, Damian Lismore

Financials (September quarter 2020): revenue nil, cash burn $544,000, cash of $13.7 million, quarters of available funding: 25

Major shareholders: Brendan Moran 3.1%, Biomérieux 3.4%, Z&F International Trading 2.24%, Mazoni Pty Ltd (Utiger Super Fund) 2%

After 14 years as an ASX-listed entity and roughly $20 million of development costs along the way, the Adelaide-based minnow is ready to sell its automated agar plate interpretation device to the world – or, more specifically, the US and Europe.

LBT's automated plate assessment system (APAS) Independence is a funky gizmo that sorts the samples automatically and then uses artificial intelligence and machine learning to determine whether they're positive or negative (and up to 85 percent are the latter).

Pathology labs should be pricking-up their shell-likes because the process reduces the role of the microbiologists who decide whether the patient has a nasty case of giardia or just a rumbling tum … or perhaps the coronavirus.

Drawing on data to date from 10,000 samples, LBT claims APAS Independence is three times faster than manual processing, handling up to 240 plates an hour.

But chief executive Brent Barnes isn't expecting the Agar Plate Whisperers' Union to picket LBT's Waymouth Street HQ. That's because these scientists are still involved in the positive readings and they've been in short supply anyway - especially during the pandemic.

"They [the laboratories] don't see this as a way to cut heads, it's more of a way to avoid hiring," Mr Barnes says.

Meanwhile, management has some explaining to do after incurring a first 'strike' on its remuneration report at this week's AGM (see below).

All the way with LBT

LBT works in a 50-50 joint venture with the Zurich-based Hettich AG, called Clever Culture Systems.

The US Food and Drug Administration approved the APAS Independence in May 2019, with the Europe's CE Mark seal of approval following in September that year.

In July this year, the company struck a European distributorship deal with the Brea, California-based clinical diagnostics giant Beckman Coulter.

"We had been working on this partnership for some time and it is a great milestone for the company," Mr Barnes says.

"Adding scale and a globally-trusted brand will enable direct access to more customers than we would have been able to achieve on our own."

In October, the company followed-up by signing a five-year licencing deal with Germany's Limbach Group.

The operator of 30 labs, Limbach plans to use the tool for detecting !!! methicillin-resistant staphylococcus aureus (MRSA or golden staph) infections.

From plate-streaking to plate-reading

LBT listed in mid-2006 on the back of its foundation product Microstreak, a device for applying samples to culture plates. It was invented by scientist John Glasson in 1979 so had a gestation period a fair bit longer than your average bacteria.

French group Biomérieux licensed Microstreak and sold 450 to 500 units under the name Previ Isola between 2007 and 2015. But Biomérieux - which remains LBTs' biggest shareholder - then handed back the rights (and a $7.9 million 'divorce' settlement) to LBT.

Advances in automation and algorithmic machine-learning led to a change of direction to automated plate assessment systems (APAS).

In late 2017, the company offloaded Microstreak - the legacy product - to China's Autobio Diagnostics who paid $2 million for a wodge of LBT shares.

Mr Barnes took over from Lusia Guthrie, the company's CEO from 2003 to 2016, who then chaired Clever Culture Systems until stepping down in mid-2018.

Hooray for FDA

In late May last year, LBT shares soared 135 percent after the company announced it had won US Food and Drug Administration approval for APAS Independence, its most advanced iteration of an automated plate reading device.

Technically, this consent was awarded to Clever Culture Systems.

Further technically, a predecessor LBT device called APAS Compact was approved for use by the FDA as far back as October 2016, with this consent related specifically to urine specimens.

APAS Compact was not intended to be commercialized. But the device, which relied on manual insertion of the plate, proved the ability of LBT's algorithms to interpret the results accurately.

"By the time you had manually loaded the instrument and taken the photo you could have done it yourself," Mr Barnes says. "But APAS Compact validated our ability to take a photo and train the algorithm to interpret the image."

LBT is ensuring the APAS Independence units are capable of processing urine samples and detecting the aforementioned MRSA, an antibiotic-resistant nasty that causes infections in multiple bodily regions.

The MRSA function is enabled by tweaking the software, although each indication needs to be specifically approved.

The company has lodged a so-called 510(k) application with the FDA and is expecting a response sometime next year.

Having a urine analysis and MRSA detection capacity is crucial, because these elements account for 70 percent of culture plate volumes in Europe.

A slow grind

So far, Melbourne's St Vincent's Hospital has purchased an APAS Independence machine, while South Australia Pathology (based at the Royal Adelaide Hospital) is also having a look-see.

In June, the company made its first US sale to the Minneapolis-based Hennepin County Medical Centre.

In July, the devices were placed into London's leading pathology group Health Services Laboratories (and arm of Australia's Sonic Healthcare) for clinical evaluation.

But decision-making times are lengthy and prospective clients are likely to want to try before they buy. "It's a long sales cycle," Mr Barnes says. "They have not budgeted for the device because they didn't know it existed."

In the US, a call centre blitz identified 1,500 prospective laboratories as potential clients, with 100 firm leads identified.

Key opinion leaders have been singing the praises of APAS Independence, including Hennepin microbiologist Dr Glen Hansen, who was impressed with the ability of the device to detect negative results from 720 urine cultures in 13 seconds.

"The US market is 50 times larger [than Australia] and the German market is 30 times bigger," Mr Barnes says.

The Australian private market is less appealing as it's dominated by three labs Healius, (formerly Primary Healthcare), Sonic Healthcare and Australian Clinical Labs.

Finances and performance

LBT's September quarter revenue of zero, zilch and zip highlight the fact that its commercialization phase has only just begun.

Still LBT can't be accused of letting the grass grow under its feet, having raised $8.4 million in July, by way of placement and share purchase plan at 16 cents apiece.

In September, the company was granted $750,000 through the MTP Connect Biomedical Translational Bridge program, to develop a module to support reading of antimicrobial susceptibility testing plates.

The company has a $4 million loan from the South Australian Government, repayable in quarterly instalments to May 2024.

Mr Barnes says investors should expect revenues to build over the next 12 months, subject to a US distributorship deal being sealed. This is expected in calendar 2021.

"It may be Beckman Coulter in a similar arrangement or someone else in a slightly different capacity."

LBT shares peaked at 58 cents in October 2016 on the initial FDA approval, but not for the first time in biotech the market's excitement was premature. The shares have traded as low as 3.7 cents (December 2011).

Oops

Your columnist wasn't there himself - he was on the wrong side of the Great Wall of Bordertown - but the 20 or so shareholders who filed into LBT's AGM in Adelaide, yesterday, witnessed more robust debate than usual.

The results show 40.6 percent of voting holders rejected the remuneration ('rem') report, well above the 25 percent threshold that deems the proposal to be rejected. The 10 percent placement capacity also fell to the 75 percent special resolution marker.

Shareholders were also less than enthused about a proposal to re-elect Kate Costello as a director, as well as three proposals to grant Mr Barnes shares in lieu of salary, a bonus and as a long-term incentive.

As with the constipated professor who worked it out with a pencil, these latter motions eventually passed.

Mr Barnes attributes the angst not so much to the 'rem' arrangements per se, but to disquiet about re-electing Ms Costello after 15 years as a director.

He argues that Ms Costello intended to "transition" as part of a board revamp, but the board "valued her long-standing history with the company".

There was also angst about the company applying a trading halt ahead of the placement, rather than letting the shares run free and - presumably - upwards. The company could then have raised the funds at a higher share price.

Mr Barnes says the board could have done a better job explaining its positions, but is resolute the company's actions were tickety-boo.

In particular, with the capital raising, the company opted for the certainty of an assured placement at a time the world was in turmoil.

The mandatory Covid-19 bit

With access to potential customer sites limited and with labs preoccupied with coronavirus testing, the Covid-19 pestilence stymied the company's sales efforts.

But Mr Barnes reports that routine testing volumes are returning to near pre-Covid levels as elective surgeries and delayed medical treatments resume.

LBT also discovered the joys of remote installation and training, with London's Health Services Laboratories equipment set up in two days.

Mr Barnes adds that the pandemic has highlighted the importance of plate automation to cope with the elevated sample volumes.

Dr Boreham's diagnosis:

LBT's potential is highlighted by the fact that 2.4 billion plates are still read manually each year.

The company reckons 1,500 US labs might be interested in the product, while there are more than 500 potential clients in Europe (currently targeting the UK, Germany and France).

The target markets are the mid-to-large laboratories processing at least 400 plates a day.

Management identifies a "revenue opportunity" of $US450,000 ($A625,000) per instrument over five years.

Put another way, a 20 percent market penetration in its targeted markets would generate instrument sales revenue of $US80 million to $US120 million of upfront capital revenue, with licencing income of $US12 million.

Of course, one has to halve this amount for LBT's profit share in the joint venture.

Mr Barnes says the company has passed the "inflexion point" of moving from development to sales - and fair enough.

But we're yet to see much of the latter.

In essence a one-product company, LBT remains a high-risk proposition - perhaps more so than what management would admit.

Still, a guide to LBT's promise is that the well-informed Biomérieux remains on the register, even though they have no strategic reason to hang around.

The Gauls' persistence signals that other investors should hang around for the pointy end of LBT's elongated commercialization journey.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Having teenaged children means your columnist lives in a 'cultured' household, but sadly not extending beyond mouldy uneaten sandwiches at the bottom of school bags.