Biotech Daily

Friday September 6, 2024

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: LBT Innovations

By TIM BOREHAM

ASX code: LBT

Share price: 1.5 cents; **Shares on issue:** 1,630,786,334; **Market cap:** $24.5 million

Chief executive officer: Brent Barnes

Board: Rebecca Wilson (chair), Brent Barnes, Brian O'Dwyer, Dan Hill

Financials (June quarter 2024): customer receipts $214,000, operating cash burn $1.178 million, cash of $2.34 million, quarters of available funding: 2

Year to June 30 2024*: revenue $1.256 million (down 41%), loss of $3.74 million ($22.25 million deficit previously), cash balance $2.35 million (up 16%)

***** The company has a $1.743 million loan from the South Australia Government, incurring 2.8 percent interest and repayable in equal tranches in April 2026 and October 2026.

Major shareholders: Unicore 13.8%, Viking BCM (Dan Hill) 13.14%, Wisplinghoff 8.1%, Brent Barnes 6%, Brendan Moran 3.5%, Richard Green 3.3%, Hettich 1.9%

Among the many witticisms attributed to Albert Einstein: insanity is doing the same thing over and over and expecting different results.

In the case of LBT, for years the company pursued a strategy of selling its automated culture plate readers to the laboratory chains before realizing it wasn't going to work.

Management's painful and sane recognition that it couldn't keep doing the same thing resulted in a $13.4 million non-cash asset write down, with the company unable to satisfy accounting standards requiring "reasonable and supportable" sales forecasts.

Following last August's reality check, LBT has turned to the pharmaceutical market, that is, helping drug makers automate and ensure quality assurance with its agar plate handling device, APAS (automated plate assessment system).

LBT's new approach has been vindicated with Astrazeneca chipping in $1 million to expedite development of a variant device, Pharma QC.

With work complete, Astrazeneca has ordered five devices, to be installed in multiple drug making facilities over the next six months.

"We also expect this to be a huge validation for us, with Astrazeneca already promoting our technology," says LBT CEO Brent Barnes.

The news is a wonderful relief for Mr Barnes, who has steered the company through a vexed period marked by a tumbling share price and diminished cash reserves.

"We have had an absolute terrific start to [the financial year] where the company has transformed into a revenue generating business," he says.

Oui, oui to LBT

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. French group Biomérieux licenced Microstreak and sold 450 to 500 units under the name Previ Isola between 2007 and 2015.

Biomérieux then handed back the rights to LBT.

Advances in automation and algorithmic machine-learning led to LBT changing direction, to automated plate assessment systems (APAS).

APAS Independence 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).

LBT claims APAS Independence is three times faster than manual processing, handling up to 200 plates an hour.

The US Food and Drug Administration (FDA) approved APAS Independence in May 2019, with the device winning Conformité Européenne (CE) mark approval in September 2021.

LBT established a 50-50 joint venture with the German-based Hettich AG, called Clever Culture Systems (CCS). At the end of 2021, LBT acquired all of CCS in a $4 million cash and scrip deal.

In 2017, LBT sold its legacy product Microstreak to China's Autobio Diagnostics.

A former Cochlear executive, Mr Barnes took over as CEO from Lusia Guthrie in 2016.

What went wrong?

LBT's long-standing premise was that the high-throughput clinical lab chains would appreciate the efficiency benefits of APAS Independence and would flock to buy it.

As it happened, they baulked at the circa $450,000 cost of the APAS units, with attached annual licence fees of around $75,000.

The company had reasoned that if it wooed the early adopters, other clients would follow. The company also had the firepower of Thermo Fisher Scientific as its global distributor.

"In reality in the last two years the product hasn't sold – that's the brutal reality," Mr Barnes says.

"Too many times I personally knocked on the doors of lab directors, CFOs and microbiologists who said they loved the product. But ultimately, budgets kept getting pushed out."

The brutal economics were that the tests are low value and mistakes are not life-threatening and easily rectified. The laboratory chains already have contracts with medical groups, so taking a bit longer to fix a test manually is not a material cost.

"There was low motivation because if you did nothing you could get by," Mr Barnes says. "Our product is nice to have, but not a must-have."

That said, LBT has sold 14 units to clinical laboratories including London's Health Services Lab (owned by the ASX-listed Sonic Healthcare).

What is going right?

After pondering other applications such as food and water testing, management zeroed-in on pharmaceutical manufacturers who need to make their high-volume biologic drugs in ultra-clean conditions.

Akin to a canary in a coal mine, agar plates are used in the clean rooms to detect pathogens. The plates are allowed four days to settle, the idea being that any nasties in the atmosphere fall into them over time.

These ‘settled plates’ are incubated over five days and then interpreted by two microbiologists.

LBT attracted the attention of Astrazeneca and the duo entered a partnership in January 2023.

The Pharma QC hardware is the same as for APAS Independence, but involves a differently-trained algorithm.

The device is simple, in that an operator loads it up and walks away (rather like a dishwasher).

APAS takes a photo, which is then interpreted by an algorithm. The colony is counted and identified automatically, with a permanent digital image of the plate embedded in the management system.

The process is three times faster than the manual system. One Pharma QC unit can process up to 1,700 plates on an eight-hour shift, freeing up the microbiologists to focus on the important plates (about 98 percent of the plates are clear).

“If there are dozens of colonies, they will all be identified consistently every time,” Mr Barnes says.

He says 1000 plates might come out of an incubator at a single facility, daily - and they all need to be read and logged into a strictly-monitored laboratory management system.

The cost of failure

Microbiologists are subject to the same frailties as any other humanoids and mistakes can happen. Often, two operators reading the same plate have different interpretations.

Running APAS Pharma QC alongside manual reading, an Astrazeneca pilot program showed that the humans missed at least one positive plate of more than 8,000 tested which was correctly identified by APAS. “APAS has not missed any plate with growth,” Mr Barnes says, with no false negatives and 100 percent detection of any plates with growth in that sample.

The cost of mistakes is high. Depending on the allowed tolerances, drug batches may need to be thrown out at great expense, but even that impost pales in comparison with the financial and reputational cost of a drug recall.

Health regulators are watching the assurance processes like a hawk and will swoop on any shortcomings.

“If a drug maker can invest in something that improves the quality and traceability and does it more effectively, that’s a high-value proposition because the cost of getting it wrong is significant,” Mr Barnes says.

The size of the prize

Mr Barnes estimates a $US2.8 billion-a-year total addressable market across 600 drug makers and about 15,000 sites, globally.

Not surprisingly, the company is focusing on the largest manufacturers with multiple facilities.

“Our customers are super sophisticated in the way they think about automation,” he says. “They don’t want to change manufacturing workflows quickly and they want to do it for all the right reasons.”

In the current half year, the company will ship eight instruments: five for Astrazeneca and one to Perth-based contract drug manufacturer Nova Cina (in a five-year deal worth $700,000).

Two demonstration units will also be sent to two other drug makers for a look-see.

The company expects Astra Zeneca to expand Pharma QC usage to additional sites.

LBT’s nearest rivals is a Massachusetts-based mob called Rapid Micro Biosystems, which combines automated plate incubation and reading.

Mr Barnes estimates Rapid Micro Biosystems has an installed base of 150 instruments. “But you need to use their proprietary media and it is double the price.”

In reality, LBT’s biggest rival is manual processing, given 98 percent of plates are still processed by hand.

Finances and performance

“We have had a great start to the financial year, with six sales recognized during the half and a couple more evaluations,” Mr Brent says.

“This is by far and away our biggest order fulfilment; and our supply and manufacturing teams are ready to deliver on that.”

LBT reported customer receipts of $214,000 in the June quarter, taking receipts for the 2023-’24 period to $1.079 million (compared with $3.8 million in the previous year).

The company had a cash burn of $1.178 million and $3.673 million for the year.

As of June 30, LBT had $2.35 million in the bank and expects to pocket a $1 million Federal Research and Development Tax Incentive and $800,000 of receivables.

The company also has 191 million listed options, exercisable at half a cent (well below the current market price). This would raise about $1 million, $800,000 of which will be used to repay half of a loan from the South Australian government

This loan was renegotiated to interest-only at 2.8 percent, repayable in equal tranches in April and October 2026 (instead of by May 2025).

Along the way, the company paid out a “terribly structured” US debt facility that was creating a valuation overhang.

The Astrazeneca contract is worth $3.4 million to $4.1m, depending on the level of annual maintenance and support over the seven-year time period.

Mr Barnes says the company expects to be cash flow positive in the December half of 2025 and is not looking to raise capital.

Late last year, LBT raised $4.5 million in a rights offer and placement. In the June quarter, $1 million of options were exercised by five shareholders, including LBT chair Rebecca Wilson and director Dan Hill.

Over the last 12 months, LBT shares have ranged between their all-time low of 0.3 cents (November 2023) and 3.8c in March this year. They peaked at 35 cents in 2016.

Dr Boreham’s diagnosis:

LBT’s problem - and it’s not unique - is that investors have become jaded by the slow commercialization and strategy whoopsies.

These include a misstep with a European distributor and discarded development of a hand-held wound management device.

To date, about $60 million has been spent on developing the APAS units.

When your columnist last assayed LBT in June 2022, the stock traded at 7.5 cents.

“We haven’t been a successful investment,” Mr Barnes concedes. “It has taken far too long and cost far too much money.

“We have been a research and development company for too many years but have come to the end of that … and are seeing early evidence of commercial success.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. You don’t have to be an Einstein to see that.