



Biotech Daily

Friday June 17, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: CYNATA, TELIX UP 4%; RESONANCE DOWN 19%**
- * **DR BOREHAM'S CRUCIBLE: LBT INNOVATIONS**
- * **TRAJAN \$30m PLACEMENT, \$20m LOAN FOR \$62m CHROMATOGRAPHY**
- * **LUMOS TO DEVELOP APTATEK PHENYLKETONURIA TEST**
- * **ARTRYA: FDA REJECTS 501(K) FOR SALIX CORONARY SOFTWARE**
- * **KAZIA: PAXALISIB ORPHAN STATUS FOR RHABDOID-TERATOID TUMORS**
- * **EBR TO RELEASE 4.6m ASX ESCROW SHARES**
- * **RECCE CONVERTS 3m 'DISPUTED' PERFORMANCE SHARES**
- * **BAILLIE GIFFORD BELOW 5% IN COCHLEAR**
- * **JM DILUTED TO 6% OF UNIVERSAL BIOSENSORS**
- * **RICHMOND HILL DILUTED BELOW 5% IN UNIVERSAL BIOSENSORS**
- * **BLACKROCK REDUCES TO 11% OF IMRICOR**
- * **MGC MARIJUANA 'KILLS GLIOBLASTOMA IN CELL LINES'**

MARKET REPORT

The Australian stock market fell 1.76 percent on Friday June 17, 2022, with the ASX200 down 116.3 points to 6,474.8 points. Eight of the Biotech Daily Top 40 stocks were up, 27 fell and five traded unchanged. All three Big Caps fell.

Cynata was the best, up 1.5 cents or 4.2 percent to 37.5 cents, with 75,779 shares traded; followed by Telix up 16 cents or 4.1 percent to \$4.06, with 1.4 million shares traded. Both Clinuvel and Polynovo climbed 3.5 percent; Uscom rose 2.9 percent; Mesoblast and Pharmaxis were up more than one percent; with Starpharma up by 0.75 percent.

Yesterday's 14.75 percent best, Resonance, led the falls, down 1.3 cents or 18.6 percent to 5.7 cents, with 883,847 shares traded. Nova Eye lost 11.9 percent; Emvision and Volpara were down more than 10 percent; Avita shed 8.3 percent; Micro-X was down 7.4 percent; Proteomics and Universal Biosensors were down more than six percent; Amplia, Compumedics, Cyclopharm, Next Science, Paradigm and Paradigm lost five percent or more; Alcidion, Medical Developments and Orthocell fell more than four percent; Actinogen, Dimerix, Imugene and Pro Medicus were down more than three percent; Impedimed and Kazia shed more than two percent; Antisense, Cochlear, CSL, Immutep and Opthea were down more than one percent; with Neuren and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: LBT INNOVATIONS

By TIM BOREHAM

ASX code: LBT

Share price: 7.5 cents

Shares on issue: 319,901,544

Market cap: \$24.0 million

Chief executive officer: Brent Barnes

Board: Joanne Moss (chair), Brent Barnes, Simon Arkell, Damian Lismore, Brian O'Dwyer

Financials (March quarter 2022): customer receipts \$424,000, operating cash burn \$218,000*, revenue nil, cash of \$5.6 million, quarters of available funding: four

*The company received \$1.03 million of government grants during the period, mainly a \$812,000 research and development tax incentive

Major shareholders: Hettich 9.6%, Brendan Moran 3%, Biomérieux 3%, Z&F International Trading 2%, Mazoni Pty Ltd (Utiger Super Fund) 2%

For most medical device companies, selling six instruments within the space of six months would hardly be cause for celebration. But for the Adelaide-based LBT Innovations, the sales "inflexion point" was an excuse to crack open a cheeky Barossa Valley sparkling given the company had only sold six devices over three years.

The orders pertain to LBT's APAS (automated plate assessment system) Independence, its lab device to automate the processing and interpreting of Petri dish (agar) samples.

Mr Barnes is encouraged because five of the orders were placed by US distributor Thermo Fisher, which signed on last September (the sixth order was jagged directly by the company).

"The company has delivered a number of extremely positive milestones over the last six months that indicate a significant turning point for the company," he says.

"I didn't expect [Thermo Fisher] to have that sort of traction in the first six months."

LBT's US push marks a change of direction for the company, which initially focused on Europe - with underwhelming results.

Nonetheless Mr Barnes recently attended the European Congress of Clinical Microbiology and Infectious Diseases, ECCMID, where 13,500 attendees heard five prezzos about APAS Independence.

On a streak ...

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).

LBT's 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).

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

The US Food and Drug Administration 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. At the end of 2021 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.

Mr Barnes took over as CEO from Lusia Guthrie in 2016.

... but Europe lags

In July 2020, LBT appointed the California-based clinical diagnostics giant Beckman Coulter as a "channel partner and lead generator" for Europe, rather than distributor.

Mr Barnes says LBT will now work with Beckman Coulter to "align our initiatives to progress our sales traction" on the Continent.

"We need a Thermo Fisher-like agreement of full service and end-to-end sales with a trusted name."

He stresses Beckman Coulter is also a trusted brand - and could well be part of the solution by way of a revamped deal.

So far, LBT has sold four units in Europe. Two were bought by London's Health Services Lab (owned by the ASX-listed Sonic Healthcare) and two were picked up by separate German laboratories.

Lessons learnt

Mr Barnes says the early US experience relative to Europe highlights the importance of getting marketing and distributor arrangements right.

The Beckman Coulter tie-up is a sales and marketing compact, by which Beckman Coulter referred clients for LBT's (one person) sales team to execute. Beckman Coulter receives basically no product margin and its salesforce is not motivated (via commissions) to go crazy on pushing LBT's product.

In contrast, the Thermo Fisher deal is a full distributor arrangement with Thermo Fisher fully servicing the client and receiving service revenue as well. Thermo Fisher is also motivated to sell APAS units to expand sales of its media products (culture plates).

"It's important for them to get margin to motivate them and understand how our product fits within their portfolio," Mr Barnes says.

Making urine analysis a wee bit simpler

LBT has been expanding its urine analysis modules to methicillin-resistant *Staphylococcus aureus* (MRSA, aka 'Golden staph'), an antibiotic-resistant nasty that causes infections in multiple bodily regions.

"Specifically, this means increasing the number of media (plate) manufacturers that are supported by APAS, which makes it easier for customers to integrate the instruments into their existing workloads," Mr Brent says.

Last year, the FDA approved a module for MRSA that works on Thermo Fisher plates and those of its nearest rival Becton Dickinson.

Similarly, the company working on an expanded urine module beyond Thermo Fisher plates.

Urine is an attractive opportunity - so to speak - because many labs put multiple specimens on one divided plate.

As you could imagine, this is not exactly best practice, but it's allowed for lab-developed tests.

The two-on-a-plate can't be automated, so the upside stems from the labs moving to the gold standard of a single-sample, automated process.

As well as (hopefully) bolstering APAS sales, Thermo Fisher's media sales double as well.

Mr Barnes says that labs want more diversity of suppliers in the post pandemic world, which means the ability to use Thermo Fisher plates as well as those of rivals.

Finances and performance

Let's do some sums

The APAS sells for about \$US300,000 for the hardware, with a \$US20,000 annual licence fee. But make that \$US30,000 in fees if the client buys extra bundles such as an antimicrobial susceptibility test in development.

Broker PAC Partners estimates a \$US100,000 cut to the distributor and \$US100,000 of cost of goods sold, leaving a \$US100,000 profit (plus annual service fee) for LBT. Over a usual contract period of five to seven years, each unit generates \$A575,000 of top-line revenue.

Take out the Thermo Fisher distribution margin and the cost of goods sold and it looks like sales of 20 to 30 units would be needed to offset LBT's current annual cash burn of \$7.5 million.

Mr Barnes says while the company expects to remain loss-making for the next 12 months, the company is "not far off" break-even, based on sales momentum. PAC Partners estimates 12 sales annually would be needed to get to this glorious juncture.

The company expects a doubling of its sales run rate in the 2022-'23 year.

In the March quarter, LBT reported net cash outflows of \$218,000, although that takes \$1.03 million of government grants (mainly a \$825,000 research and development receipt) into account. The company has cash of \$5.6 million, which along with research and development monies and sales revenue provides a 12-month funding runway.

"I'll take the old politician's line that the board is always looking at funding options," Mr Barnes says.

LBT has availed of a \$4 million low-interest loan from the South Australian government, which has been repaid at the rate of \$250,000 per quarter and will be fully discharged in November.

Over the last 12 months, LBT shares have ranged between eight cents (mid-May) and 14 cents (September 2021). Over the last five years they have been as high as 33 cents (July 2017) and as low as six cents (March 2019).

Sizing the market prize

About 2.4 billion lab plates are read manually each year.

LBT estimates a total addressable market of 2,000 labs in the countries where APAS Independence has been launched: Australia, Britain, Germany, France and the US.

The latter accounts for 1,500 of these labs, which are deemed to be at least mid-sized facilities processing more than about 400 plates a day.

In May this year, management was heartened to make a direct sale to New York's Albany Medical Centre, which only does about 200 plates a day.

This implies a broader market among the smaller labs and the reason is acute shortages of skilled labour.

According to the US newsletter Laboratory Economics, medical technologists in the San Francisco area are commanding salaries of \$US150,000 to \$US180,000 per year, with sign on bonuses of more than \$US25,000.

Says one of the healthcare recruiters quoted in the article: "Lab employees had always been treated like the red-headed stepchildren of healthcare, but the pandemic has raised their recognition and pay."

Mr Barnes says the situation is similar here, with such roles paying about \$A145,000 a year.

Mr Barnes notes the culture plate market is growing at seven to eight percent as testing expands into areas such as routine MRSA screening in hospitals.

Dr Boreham's diagnosis:

Mr Barnes says investors are justified in querying why the 22-year-old company has only sold a handful of instruments after such an effluxion of time.

"As a shareholder, I empathise with this frustration," he says. "The company retains focus on what it has control over, which is delivering what we say we will deliver.

"We have achieved important milestones over the last 12 to 18 months but it has taken us longer than we thought."

The pandemic-induced bottlenecks didn't help, of course, and the company needed to get its ducks in a row with appointing key opinion leaders and getting cited in learned publications.

But with a US distributorship made in heaven (our words) and Europe in remedial mode, Mr Barnes says LBT should be able to sell "hundreds" of instruments over time.

Ultimately, LBT's success will depend on whether the units are 'must have' for the targeted labs, or a 'nice to have'.

If the vaunted return on investment for a typical client in these times of elevated lab salaries holds true, sales should speak for themselves.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has nothing against red-headed step-children, but does get the feeling he entered the wrong profession.

TRAJAN

Trajan says it expects to raise \$29.7 million and borrow \$20 million to acquire Chromatography Research Supplies for \$US43.3 million (\$A61.6 million).

Trajan said that in addition to the fully underwritten placement at \$2.00 a share, the acquisition of the Louisville, Kentucky-based Chromatography Research Supplies would be funded by a \$20 million loan from HSBC, and \$13.4 million from its existing cash reserves.

The company said it would offer a share plan to holders at the record date or June 16, with the plan to open on June 24 and close on July 12, 2022.

Trajan said the offer price of \$2.00 a share was a an 11.1 percent discount to the last closing price of \$2.25 on June 16, 2022.

The company said that Canaccord Genuity (Australia) and Ord Minnet were joint lead managers and underwriters to the placement with DLA Piper the legal adviser.

Trajan said Chromatography Research Supplies was a manufacturer of "high quality analytical consumables" including manual crimping tools, gas filters, ferrules and injection port septa.

Trajan said the acquisition would result in forecast revenues for the year to June 30, 2022 of \$US14.1 million, and earnings per share growth for the following year of more than 42 percent including identified corporate savings and product line synergies.

Trajan managing-director Stephen Tomisich said the acquisition "enhances multiple areas of our business and builds on our previous successful acquisitions to deliver comprehensive and best in class products in the analytical workflow."

"As with our previous acquisitions, we have partnered with CRS for many years, understand their business, and know precisely where they fit within Trajan," he said.

"The acquisition is earnings accretive and able to be rapidly integrated," Mr Tomisich said.

"Our market leadership in gas chromatography is enhanced with the addition of septa and ferrules components, as well as introducing a broader portfolio of products in other areas of the analytical workflow that build on our automation business," Mr Tomisich said.

Trajan said it had requested a trading halt "to allow the placement to take place in an orderly fashion" and last traded at \$2.25.

LUMOS DIAGNOSTICS

Lumos says it will receive at least \$US500,000 (\$A712,000) to develop an at-home phenylketonuria screening test for Aptatek Biosciences Inc.

Lumos said that phenylketonuria was a rare inherited disorder, which caused the amino acid phenylalanine to build up in the body leading to intellectual disabilities, seizures, behavioral problems and mental disorders.

The company said it expected to earn at least \$US500,000 from the Princeton, New Jersey-based Aptatek in the initial phase of the agreement for the production of an assay and reader, expected by the end of this year.

Lumos said there was further potential revenue from additional development activities and ongoing instrument manufacturing in subsequent phases of the agreement.

The company said the phenylketonuria diagnostic had US Food and Drug Administration breakthrough status, which was expected to accelerate its approval.

The company said Aptatek intended to begin further studies and activities using the test by April 2023, with a US commercial launch expected later in 2023.

Lumos said that subject to regulatory approvals and a commercial manufacturing contract Aptatek intended to hire Lumos as the instrument manufacturer.

Lumos was unchanged at 14.5 cents.

[ARTRYA](#)

Artrya says the US Food and Drug Administration it has not cleared the 510 (k) application for approval of its Salix coronary anatomy software.

Artrya said it expected to be able to address the issues raised by the FDA and would consider other pathways based on the FDA's commentary regarding the application.

Last year, the company said that Salix used artificial intelligence to automate the analysis and diagnosis of heart computed tomography (CT) scans, to help clinicians identify and manage patients at risk of a cardiac arrest, with a single CT scan able to detect and assesses the presence of vulnerable plaque in a patient's arteries in about 15 minutes (BD: Oct 19, 2021).

Today, Artrya said it would hold a conference call on Monday June 20, 2022 to discuss the FDA application.

Artrya fell 10 cents or 17.9 percent to 46 cents with 1.1 million shares traded.

[KAZIA THERAPEUTICS](#)

Kazia says the US Food and Drug Administration has granted orphan drug designation to paxalisib for the paediatric brain cancer atypical rhabdoid-teratoid tumors.

In 2020, Kazia said the FDA had granted paxalisib orphan designation for malignant glioma, rare paediatric disease designation for diffuse intrinsic pontine glioma and fast track designation for glioblastoma (BD: Aug 7, 20, 24, 2020).

Today, the company said the FDA orphan status, for diseases with fewer than 200,000 cases a year, would save it about \$3 million in fees usually associated with the regulatory process, and grant it up to seven-years in which other companies were unable to use its data to create a generic version of the drug.

Kazia said that initial results from a phase II trial combining several investigational drugs, including paxalisib, in the treatment of patients with diffuse midline gliomas, were due in 2023, and that final data from a phase I trial of paxalisib for diffuse intrinsic pontine glioma was expected by the end of 2022.

Kazia chief executive officer Dr James Garner said "childhood brain cancer has emerged as an important area of focus for the paxalisib program".

"We have been working for some years with several world-leading researchers in [diffuse intrinsic pontine glioma], one of the most aggressive childhood cancers," Dr Garner said.

Dr Garner said recent data showed the potential of paxalisib in atypical rhabdoid-teratoid tumors "another form of childhood brain cancer that is very poorly served by existing treatments".

Kazia fell 1.5 cents or two percent to 74.5 cents.

[EBR SYSTEMS](#)

EBR says it will release 4,591,477 Chess depository interests from ASX escrow on June 24, 2022.

According to its most recent filing, EBR would have 262,986,529 shares available for trading following the release from escrow, with a further 6,335,639 shares in ASX escrow, for a total of 269,321,898 shares on issue.

EBR was up three cents or 7.5 percent to 43 cents.

RECCE PHARMACEUTICALS

Recce says it will convert 2,712,498 performance shares, held by former directors and management staff, "following the resolution of a dispute".

Recce did not disclose the nature of the dispute.

In announcements on June 26 and August 17, 2020, Recce referred to the issue of performance shares on August 20, 2015, before it listed on the ASX, and said it had determined that 1,356,249 Class C and 1,356,249 Class D performance shares, held by former directors and key management personnel of the company, were ineligible for conversion, and as a result would not be converted into fully paid ordinary shares.

The Recce prospectus did not detail who held the performance shares.

Recce fell 1.5 cents or 2.5 percent to 59 cents.

COCHLEAR

Baillie Gifford and its affiliates say they have reduced their Cochlear holding below five percent, ceasing to be substantial shareholders.

The Edinburgh-based company said that in more than 200 transactions between November 17, 2021, and June 16, 2022, it bought, sold, and withdrew shares, with the largest single sale 47,100 shares for GBP5,908,251 (\$A10,285,973), or \$218.39 a share. Cochlear fell \$2.87 or 1.5 percent to \$188.98 with 388,198 shares traded.

UNIVERSAL BIOSENSORS

JM Financial says it has reduced and been diluted in Universal Biosensors from 13,731,464 shares (7.39%) to 13,443,319 shares (6.34%).

In May, Universal Biosensors said it would raise \$20 million in a one-for-6.85 entitlement offer at 77 cents per Chess depositary interest (BD: May 18, 2022).

Today, the Melbourne-based JM said that between June 2 and 6, 2022 it sold 276,432 shares for \$124,394, or 45 cents a share.

Universal Biosensors fell 2.5 cents or 6.85 percent to 34 cents.

UNIVERSAL BIOSENSORS

Melbourne's Richmond Hill Capital says it has increased its holding but been diluted below five percent in Universal Biosensors, ceasing to be a substantial shareholder.

Today, Richmond Hill said that between May 5 and June 16, 2022, it bought 1,825,925 shares in Universal Biosensors, for \$895,114, or 49 cents a share (see above).

IMRICOR MEDICAL SYSTEMS

Blackrock says it has reduced its substantial holding in Imricor from 17,529,317 shares (12.23%) to 16,102,886 shares (11.23%).

The New York-based Blackrock said that between January 27 and June 15, 2022, it had bought and sold shares at prices ranging from \$1.02 to 16 cents a share.

Imricor fell 3.5 cents or 23.3 percent to 11.5 cents with 2.6 million shares traded.

[MGC \(MEDICAL GRADE CANNABIS\) PHARMACEUTICALS](#)

MGC claims that a three-year, Slovenian study shows that its marijuana derivatives kill the brain cancer glioblastoma in cell lines.

MGC said it experimented on glioblastoma cells from 18 patients using combinations of tetrahydrocannabinol (THC), cannabidiol (CBD) and “cannabigerol” (CBG) and said that they were “cytotoxic to glioblastoma tumor and stem cells, reducing the cells’ viability and inducing caspase-dependent cell apoptosis, or cell death”.

The company provided four graphs, but no significant data to support its claims.

MGC fell 0.3 cents or 13.0 percent to two cents with 14.9 million shares traded.