



Biotech Daily

Friday November 27, 2020

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.53 percent on Friday November 27, 2020, with the ASX200 down 35.3 points to 6,601.1 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and one was untraded.

Optiscan was the best, up 0.5 cents or five percent to 10.5 cents, with 332,952 shares traded. Kazia, Nova, Oncosil and Uscom climbed more than three percent; Medical Developments and Volpara rose more than two percent; Antisense, Compumedics, Genetic Signatures and Nanosonics were up one percent or more; with Clinuvel, Cochlear and Opthea up by less than one percent.

Imugene led the falls, down 0.5 cents or 4.8 percent to 10 cents, with 48.1 million shares traded. Both Actinogen and Neuren fell 4.35 percent; both Alterity and Resonance retreated three percent; Amplia, Next Science, Orthocell and Paradigm shed two percent or more; Avita, CSL, Pharmaxis and Starpharma were down more than one percent; with Mesoblast, Polynovo, Pro Medicus and Resmed down by less than one percent.

[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 about 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 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 wedge 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 "inflection 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.

CONTROL BIONICS

Melbourne's Control Bionics says its \$15 million initial public offer at 60 cents a share has closed oversubscribed ahead of its proposed ASX listing on December 7, 2020.

Control Bionics chief executive officer Rob Wong told Biotech Daily that the company's Neuronode Trilogy was able to convert thoughts to computerized actions including typing, speaking and telephone conversations.

Mr Wong said that users who were clearly unable to move or speak were able to answer a telephone and have a conversation.

Mr Wong said the Neuronode Trilogy device had US Food and Drug Administration and Australian Therapeutic Goods Administration approval as well as Conformité Européenne (CE) marking.

He said the company would use the funds raise to expand commercialization of the device which was already generating revenue.

Mr Wong said that the wrist-watch sized Neuronode Trilogy could convert brain signals to computerized actions using muscle signals obtained from anywhere that has muscle tissue including arms, legs, feet and even forehead.

He said that a quadriplegic user was surprised when the company was able to pick up and use a signal from his palm.

Mr Wong said that although there were similar devices and most people were aware of the system used by the late Prof Stephen Hawking, the Neuronode Trilogy had the advantage of "faster speeds and less fatigue".

Mr Wong said that when the initial public offer was completed the company would have a notional market capitalization of \$50 million and would list under the code CBL.

According to the Control Bionics website the inventor and founder Peter Ford is the director of innovation with chair Roger Hawke and a board comprising former Biota chief financial officer Damian Lismore along with former Lazard Private Equity managing-director Lindsay Phillips and Brett Crowley as company secretary.

Mr Wong said that Morgans was the lead broker to the offer.

The prospectus is at: <https://investor.automic.com.au/#/ipo/controlbionics>.

Control Bionics is a public unlisted company.

FEDERAL GOVERNMENT

The Federal Government says it will provide \$4 million for six Covid-19 research projects examining both the virus and the response to the pandemic.

A media release from Federal Health Minister Greg Hunt said that the grants aimed "to develop high priority digital health infrastructure, improving the speed and features of health system responses during acute crises".

"Each of these projects has the ability to assist and inform government responses to the pandemic and continue our improvements to health outcomes," Mr Hunt said.

The media release said that Melbourne's Monash University would receive \$1,922,584 for a national data management platform and "learning health system"; \$810,300 for real-time modelling of Australia's Covid-19 response; and \$315,961 for a project on the effectiveness of tailored Covid-19 messaging for vulnerable Australians

The Government said it would provide Sydney Local Health District with \$670,406 for integrating remote monitoring technology into digital health infrastructure; with Melbourne's Deakin University receiving \$109,047 for inclusive health communication in specialist disability accommodation; and Sydney's Macquarie University would be awarded \$174,992 for "harnessing the health communication power of the early childhood sector".

ANTEOTECH

Anteo says it has received \$1,195,634 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Anteo said the rebate related to expenditure for the year to June 30, 2020.

Anteo fell 0.3 cents or three percent to 9.7 cents with 11.8 million shares traded.

OPYL AI

Opyl says it has received \$249,001 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Opyl said the rebate related to expenditure for the year to June 30, 2020.

Opyl was up one cent or 7.4 percent to 14.5 cents.

RESAPP HEALTH

Resapp says 35 percent of its annual general meeting opposed 500,000 options to director Dr Michael Stein and the 10 percent placement capacity was lost.

Resapp said the proposal to issues Dr Stein incentive options had 81,443,170 votes (35.24%) opposed and 149,657,340 votes (64.76%) in favor.

The company said the 10 percent placement facility, which needed a 75 percent majority to pass, was opposed by 69,068,861 votes (27.23%) with 184,604,588 votes (72.77%) in favor.

Rasapp said the highest percentage opposition was 35.28 percent of votes against the ratification of shares issued in the February placement, while the ratification of shares issued under the device development agreement was opposed by 28.51 percent.

The company said the remuneration report faced up to 22.98 percent opposition and the re-election of directors Chris Ntoumenopoulos and Dr Stein passed with up to 21.48 percent and 17.05 percent of the meeting, respectively, opposed.

Resapp said the replacement of the constitution and the appointment of an auditor passed more easily.

According to the company's most recent Appendix 2A new issue announcement, Resapp had 758,119,489 shares on issue, meaning the votes against Dr Stein's options amounted to 10.7 percent of the company, sufficient to call extraordinary general meetings.

Resapp was up 0.2 cents or 2.2 percent to 9.2 cents.

SOMNOMED

Somnomed says its annual general meeting has passed all resolutions, but with 12.27 percent of the meeting opposed to the election of Hilton Brett as a director.

Somnomed said Mr Brett faced 5,251,287 opposing votes (12.27%), with 37,555,950 votes in favor.

The company said the election of Hamish Corlett as a director was opposed by 9.11 percent of the meeting, while the remaining resolutions, including the remuneration report, the appointment of an auditor and the election of directors Guy Russo, Amrita Blickstead and Michael Gordon were passed overwhelmingly.

According to the company's annual report, Somnomed had 82,759,315 shares on issue, meaning the votes against Mr Brett's election amounted to 6.35 percent of the company, sufficient to call extraordinary general meetings.

Somnomed fell two cents or 0.9 percent to \$2.16.

BARD1 LIFE SCIENCES

Bard1 says it withdrew the resolution to re-elect director Helen Fisher before the annual general meeting which saw 7.76 percent opposition to share consolidation.

Bard1 said the share consolidation received 83,626,172 opposing votes (7.76%) with 993,365,625 votes (92.24%) in support.

Earlier this week, the company said director Ms Fisher, who was appointed in July, had stepped down to “focus on new opportunities” (BD: Jul 29, Nov 25, 2020).

Today, Bard1 said the remaining resolutions passed more easily, including the remuneration report, the 10 percent placement capacity and the election of directors Prof Allan Cripps and Dr Geoffrey Cumming.

According to the company’s annual report, Bard1 had 2,394,530,384 shares on issue, meaning the votes against the share consolidation amounted to 3.5 percent, not sufficient to call extraordinary general meetings.

Bard1 was up 0.1 cents or 4.35 percent to 2.4 cents with 2.9 million shares traded.

LITTLE GREEN PHARMA

Little Green Pharma says its annual general meeting has passed all resolutions but with 9.14 percent dissent to the 10 percent placement capacity.

Little Green Pharma said that “Resolution 7,” the 10 percent placement facility, had 6,552,969 votes (9.14%) against, with 65,149,936 votes (90.86%) in favor.

The company said the remaining resolutions including the remuneration report and the issue of shares to directors in lieu of salary passed easily.

According to the Little Green’s most recent appendix 2A new issue notice, the company had 78,871,324 shares on issue, meaning the votes against the placement capacity amounted to 8.3 percent of the company, sufficient to call extraordinary general meetings.

Little Green was up 2.5 cents or 5.3 percent to 49.5 cents with 2.2 million shares traded.

NUHEARA

Nuheara says 96 percent of its annual general meeting has blocked the election of Warwick Sauer as director, with all other resolutions passing easily.

In its notice of annual general meeting, Nuheara said Mr Sauer was a shareholder with 100 shares in the company who had nominated himself as a non-executive director, and the board did not support his election.

Today, Nuheara said Mr Sauer’s election was opposed by 334,244,998 votes (96.02%), with 13,842,127 votes (3.98%) in favor.

Nuheara was up 0.2 cents or 4.1 percent to 5.1 cents with 3.2 million shares traded.

TALI DIGITAL

Tali has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the share price rose 43.3 percent from 3.0 cents yesterday, November 26, to a high of 4.3 cents today, November 27, 2020, and noted a “significant increase” in the trading volume.

Tali said the company’s performance and objectives presented at its annual general meeting earlier this week had “generated significant interest”, particularly in regard to its early childhood attention intervention program.

Tali closed up 0.8 cents or 26.7 percent at 3.8 cents with 112.2 million shares traded.

TELIX PHARMACEUTICALS

Telix has requested a trading halt “pending an announcement regarding a proposed commercial acquisition”.

Trading will resume on December 1, 2020 or on an earlier announcement.

Telix last traded at \$3.25.

IMMUTEP

Sydney’s Australian Ethical Investment says its 41,583,333 shares in Immutep have been diluted from 8.44 percent to 6.75 percent following a capital raising.

Last week, Immutep said it raised \$29.6 million in a placement at 24 cents a share, with Australian Ethical listed as a key investor (BD: Nov 19, 2020).

Immutep was unchanged at 26.5 cents with 1.6 million shares traded.

ALTERITY HEALTH

Regal Funds Management says it has become a substantial shareholder in Alterity with 262,791,109 shares or 12.94 percent of the company.

The Sydney-based Regal Funds said that between October 23 and November 24, 2020 it bought 309,369,113 shares for \$11,446,657 or 3.7 cents a share.

Regal Funds did not disclose whether it sold any shares in the period as required under the Corporations Act (Regulatory Guide 159.263).

Alterity fell 0.1 cents or three percent to 3.2 cents with 10.4 million shares traded.

BTC HEALTH

Peter Jones and Helen Jones say they have reduced their holding in BTC from 16,984,323 shares (6.95%) to 14,517,704 (5.91%).

Mr Jones said that between July 2, 2019 and November 14, 2020 they sold 2,466,619 shares for \$221,215 or an average of nine cents a share.

BTC was unchanged at nine cents.

LIVING CELL TECHNOLOGIES

Jimmy Thomas and Ivy Ponniah say they have become substantial in Living Cell with 30,069,031 shares or 5.26 percent of the company.

The Melbourne-based Mr Thomas and Ms Ponniah said that between March 26 and November 23, 2020 they bought the shares for \$569,871 or an average of 1.9 cents a share.

Living Cell was unchanged at 1.4 cents.

NEUROTECH INTERNATIONAL

Neurotech has requested a voluntary suspension to follow the trading halt regarding “further results of the in-vitro cell studies of its cannabis strains” (BD: Nov 25, 2020).

Trading will resume on November 30, 2020 or on an earlier announcement.

Neurotech last traded at 2.9 cents.

[ESENSE-LAB](#)

Esense says in-vitro tests have shown that two blends of its marijuana terpene compounds are “effective at neutralizing [human-coronavirus-OC43]”.

Esense said human-coronavirus-OC43 was a weak strain of human coronavirus, which was related to severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), the virus that caused Covid-19.

The company said its terpene compounds, TRP-ENV and TRP-COV, showed a “significant” reduction in the viral copy numbers and a neutralization efficiency “at least as good as 70% ethanol”.

Esense was in a suspension and last traded at 1.8 cents.