Biotech Daily

Friday September 6, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CYCLOPHARM UP 7%; MEDADVISOR DOWN 8%**

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*** COMPUMEDICS EXPECTS REVENUE UP 11% TO $55m, EBITDA UP 100% TO $5m**

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*** CLINUVEL: PRINGLE, VAN DIEVOET, DR GRIMES REPLACE SHANAHAN**

MARKET REPORT

The Australian stock market was up 0.39 percent on Friday September 6, 2024, with the ASX200 up 31.0 points to 8,013.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, 19 were down, four traded unchanged and one was untraded.

Cyclopharm was the best, up 10 cents or 7.1 percent to $1.50, with 18,389 shares traded. Clarity and Resonance climbed more than five percent; Syntara was up 3.3 percent; Atomo, Cynata, Impedimed, Orthocell, Paradigm, Percheron and Proteomics rose more than two percent; Amplia, Polynovo, Pro Medicus, Resmed and Telix were up one percent or more; with Avita and CSL up by less than one percent.

Medadvisor led the falls, down three cents or eight percent to 34.5 cents, with 944,051 shares traded. Medical Developments and Nova Eye fell five percent or more; 4D Medical and Imugene lost more than three percent; Aroa, Curvebeam, Dimerix, Mesoblast, Neuren, Opthea and SDI shed more than two percent; Alcidion, Cochlear, Compumedics, Immutep and Micro-X were down more than one percent; with Clinuvel and Genetic Signatures down by less than one percent.

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%) (LBT 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, Pharma QC. With work complete, Astrazeneca 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 Germany's 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. And in 2017, LBT sold its legacy 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. But they baulked at the $450,000 cost per unit, with 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.

UNIVERSITY OF MELBOURNE, FLOREY INSTITUTE

The University of Melbourne says it has adapted “inorganic, analytical geo-chemistry” to search for and analyze early biomarkers of Alzheimer’s disease in blood.

The University of Melbourne said the research, in collaboration with the Florey Institute, compared the levels of potassium isotopes in blood serum in 10 healthy patients and 10 patients with Alzheimer's disease.

The University said it hoped to reduce the impacts of dementia through the development of its blood test.

The University of Melbourne’s Dr Brandon Mahan said “our minimally invasive test assesses the relative levels of potassium isotopes in human blood serum and shows potential to diagnose [Alzheimer’s disease] before cognitive decline or other disease symptoms become apparent, so action can be taken to reduce the impacts”.

“Our test is scalable and … unlike protein-based diagnostics that can break down during storage … it avoids sample stability issues because it assesses an inorganic biomarker,” Dr Mahan said.

“Earlier diagnosis would enable earlier lifestyle changes and medication that can help slow disease progression and would allow more time for affected families to take action to reduce the social, emotional and financial impacts of dementia,” Dr Mahan said.

“It could also make patients eligible for a wider variety of clinical trials, which advance research and may provide further medical benefits,” Dr Mahan said.

The Florey Institute’s Prof Ashley Bush said “our blood test successfully identified [Alzheimer’s disease] and shows diagnostic power that could rival leading blood tests currently used in clinical diagnosis”.

The University said that the research, titled ‘Stable potassium isotope ratios in human blood serum towards biomarker development in Alzheimer's disease’, was published in the journal Metallomics, with the full article available at: https://bit.ly/3z98AHm.

ENA RESPIRATORY

ENA says the US Department of Defense has granted $US3.18 million ($A4.72 million), adding to its previous $US8.18 million for its anti-viral INNA-051.

Last year, Ena said the US Government had awarded it $3.8 million for a phase II INNA-051 program for community-acquired viral respiratory infections, in addition to its $4.38 million initial funding (BD: Aug 31, 2023).

At the time, the company said INNA-051 was a “first-in-class, intra-nasal, innate immune modulator for the prevention of complications associated with respiratory viral infections in at-risk populations”.

Today, Ena said it would use the proceeds to expand the phase Ib trial of its INNA-051 dry powder formulation from only patients older than 60 to include adults aged 16 to 45, as well as support “product optimization” ahead of its phase IIb initiation.

The company said results were expected by January 2025, with the contract awarded by the Department of Defense’s Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, the Joint Project Manager for Chemical, Biological, Radiological, And Nuclear Medical, in collaboration with the Defense Innovation Unit.

Ena chief executive officer Dr Christophe Demaison said the funding was “further recognition of the potential of INNA-051 to play a significant role in protecting individuals at risk of serious harm from respiratory viral infections, including those with occupational risk”.

ENA is a private company.

VICTORIA GOVERNMENT

The Victoria Government says it will grant $2.1 million to 15 Victorian mRNA research projects, including for HIV, inflammatory disease and cancer.
The Victoria Government said Melbourne's St Vincent's Institute of Medical Research would receive $100,000 to develop new treatments for non-alcoholic fatty liver disease using mRNA editing technology.
A media release from the Victoria Treasurer an Minister for Economic Growth Tim Pallas said other recipients include Messenger Bio, who were researching mRNA therapeutics for genetic brain diseases, and the Walter and Eliza Hall Institute's gene therapy research for inflammatory disease.
Mr Pallas said "this investment will support institutions like St Vincent's Institute of Medical Research to save lives and grow our thriving biotech sector".
"We're backing our world-class local researchers to discover the next generation of life-saving vaccines and medicines, and cementing Victoria as the leading hub for mRNA research in the Asia Pacific," Mr Pallas said.
St Vincent's Institute of Medical Research director Prof Tom Kay said that the "investment in medical research gives St Vincent's Institute of Medical Research scientists the best chance of maximizing new mRNA technology to develop leading-edge therapy to combat conditions like liver disease".

ECHO IQ

Echo IQ says it has 'firm commitments' to raise about $7.1 million through an institutional placement at 15.0 cents a share.
Echo IQ said the placement was "strongly supported by both new and existing institutional investors".
The company said that the funds would go towards commercialization of its cardiology software, product development and its "cash runway" through the US Food and Drug Administration approval for its heart failure technology.
Echo IQ said the issue price was a 5.4 percent discount to the five-day volume weighted average price.
The company said that Ord Minnett was the lead manager to the placement.
Echo IQ was up 2.5 cents or 15.6 percent to 18.5 cents with 9.3 million shares traded.

COMPUMEDICS

Compumedics says it expects revenue for the year to June 31, 2025 to be up about 10.7 percent to more than $55 million.
Compumedics said it expected earnings before interest, taxes, depreciation and amortization (Ebitda) to double to about $5 million.
Last week, Compumedics said revenue for the year to June 30, 2024 was $49,719,000 with net loss after tax $499,000 and Ebitda $2.5 million (BD: Aug 30, 2024).
Today, the company said its revenue increase was driven primarily by its software-as-service products that necessitated "ongoing investment in sales and marketing" that would impact Ebitda increases.
Compumedics said Ebitda for the year to June 30, 2024 was $2.5 million, up from a $2.0 million loss the previous year due to increased sales of $7.5 million (including its $4.7 million sale of its magneto-encephalography technology to China's Tianjin Normal University) and an increase in margins from 5 1 percent to 52 percent.
Compumedics fell half a cent or 1.5 percent to 32 cents.

LUMOS DIAGNOSTICS HOLDINGS

Lumos says its one-for-1.82 pro rata institutional entitlement offer has raised $3.1 million, with its retail offer to raise $6.9 million more.
Earlier this week, Lumos said it hoped to raise $10.0 million through a $4.0 million institutional offer and a $6.0 million retail offer at 3.8 cents a share (BD: Sep 4, 2024).
Lumos fell 0.4 cents or 8.7 percent to 4.2 cents with 3.6 million shares traded.

ORTHOCELL

Orthocell says its distributor Biohorizons Implant Systems has reported the first sale in Canada of its Striate+ for dental guided bone and tissue regeneration.
In July, Orthocell said Health Canada granted it a medical device licence for Striate+, and Biohorizons was seeking approvals in other jurisdictions (BD: Jul 11, 2024).
Orthocell was up one cent or 2.6 percent to 40 cents.

BIOTRON

Biotron says its up-to 60 patients, randomized, phase II trial of BIT225 for Covid-19 met primary safety and tolerability endpoints, but did not meet its primary efficacy endpoint.
In 2023, Biotron said it would begin a double-blinded trial of BIT225 for Covid-19 in Thailand to determine the safety, tolerability and efficacy of 200mg and 400mg doses of BIT225 per day for seven days in patients diagnosed with Covid-19 within three days of symptoms, compared to a placebo group (BD: May 4, 2023).
At the time, the company said primary efficacy objectives were safety, severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) nasal viral load, kinetics of change and the time it took to achieve a negative polymerase chain reaction (PCR) test.
Today, Biotron said there was “no statistically significant differences between drug and placebo groups based on change in Sars-Cov-2 nasal viral load, kinetics of change or time to negative Sars-Cov-2 [polymerase chain reaction] when compared to baseline values on day one to dosing completion on day seven”.
The company said observed adverse events were “congruent in severity and frequency” as those seen in previous BIT225 trials.
Biotron said that it noticed, only once the dataset was complete and unblinded, that four patients did not demonstrate quantifiable levels of virus on day-1, resulting in a post-hoc exploratory evaluation from day-3 to day-9, and that in this analysis nasal viral load decline slowed in placebo after day-6 while continuing at a “relatively consistent rate in the two BIT225 dosage groups” which led to lower viral loads in the BIT225 groups ($p = 0.02$).
The company said that, while “of interest … and potentially informing further study of BIT225 in Sars-Cov-2 infection, these post hoc exploratory analyses do not change the formal outcomes of the trial”.
Biotron said the trial was “restricted by Thai health and regulatory authorities to recruiting only those individuals with low to moderate risk of severe COVID-19, and under 60 years of age” and that “a number of the drug-related adverse events seen with BIT225 in this, and previous trials, are identical to Sars-Cov-2-related symptoms, which made apportioning causality and efficacy difficult”.
Biotron chief executive officer Dr Michelle Miller said “we remain optimistic re the potential of this new class of drugs to target significant viral infections, including Sars-Cov-2”.
“The widespread availability of vaccination as well as immunity due to prior infection with Sars-Cov-2 contribute to challenges in demonstrating clinical efficacy,” Dr Miller said.
Biotron fell 1.1 cents or 39.3 percent to 1.7 cents with 32.8 million shares traded.

ARGENICA

Argenica says it has dosed 43 of 92 patients in its phase II trial of ARG-007 for acute ischaemic stroke, with no adverse events and all 10 sites administering doses.
Earlier this year, Argenica said it had dosed the first cohort in the study, with no adverse events reported; in April it said following five-patient safety data it had approval to continue the trial; in July it said it had opened eight of 10 trial sites and dosed 20 of up-to 92 patients in its single-dose, placebo-controlled, phase II trial of ARG-007 for acute ischaemic stroke (BD: Apr 10, Apr 29, Jul 24, 2024).
Today, the company said its independent data safety monitoring board had recommended the trial continue, with no modifications to the study protocol.
Argenica said it expected to finish doing all patients by July 2025.
Argenica was up 1.5 cents or 1.9 percent to 80 cents.

IMMURON

Immuron says it plans to file an investigational new drug application for IMM-529 for Clostridioides difficile infection by July 2025, followed by a phase II trial.
Immuron said it had received “favorable feedback” from the US Food and Drug Administration on its pre-investigational new drug submission for IMM-529 and that previous clinical data “provided support” for the continued development, including its research with Melbourne’s Monash University to develop vaccines to produce cow colostrum-derived antibodies.
The company said an unintended consequence of anti-microbial treatment was disruption of the gastro-intestinal microbiota, which led to susceptibility to pathogens like Clostridioides difficile, which in turn relied on antibiotics for treatment, not allowing gut flora to regenerate.
Immuron said that, in the US, Clostridioides difficile impacted more than 400,000 people and contributed to 30,000 deaths each year.
Immuron was unchanged at 9.5 cents.

CLEO DIAGNOSTICS

Cleo says it has recruited the first of “a minimum of 500 patients” in a US trial of its ovarian cancer blood test.
Cleo said eight medical institutions in six US states were currently recruiting patients, with data to underpin a US Food and Drug Administration submission for the approval of its blood test for clinical use.
Cleo chief executive officer Dr Richard Allman said “commencement of our US trials confirm a significant milestone for Cleo and sets a clear pathway now for our planned entry into the US”.
“We have already demonstrated that Cleo’s ovarian cancer blood test is highly accurate, can detect early-stage cancer, and importantly is significantly better than clinical tools used today,” Dr Allman said.
“It is important to note that no diagnostic test exists today for ovarian cancer … diagnosis can only be made after surgery,” Dr Allman said.
“The opportunity in front of us is immense and Cleo is well positioned and funded to achieve access into our initial pre-surgery test market,” Dr Allman said.
Cleo was up three cents or 8.3 percent to 39 cents.

NOXOPHARM

Noxopharm says it has a $1.8 million loan from Endpoints Capital at 15.8 percent annual interest ahead of its Federal Government Research and Development tax Incentive.
Noxopharm said the loan was repayable from the proceeds of its tax incentive, which was expected to be about $2.3 million for the year to June 30, 2024.
Noxopharm fell 1.5 cents or 12.0 percent to 11 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says Matthew Pringle, Guy Van Dievoet and Dr Pearl Grimes will replace non-executive director Brenda Shanahan, effective from September 6, 2024.
Clinuvel said Ms Shanahan joined the board in 2007 and was chair from late 2007 until July 2010, as well as chair of the audit and risk committee.
The company said Mr Pringel had been a partner at Pitch Partners for more than 25 years, and was a director of Navalo Financial Services Group, Hypersonix Launch Systems and Anglicare Victoria.
Clinuvel said Mr Van Dievot had worked for the Belgium-based merchant bank Indoseuz, Amsterdam's ABN-AMRO bank, and Paris' Bank BNP Group, and had been an executive director for Meespierson.
The company said Dr Grimes was founder and director of the Vitiligo and Pigmentation Institute of Southern California, and director of the Grimes Institute for Medical and Aesthetic Dermatology, as well as professor of dermatology at the University of California Los Angeles (UCLA).
Clinuvel chair Prof Jeffrey Rosenfeld said "on behalf of the board, I wish to sincerely thank Ms Shanahan for her extensive contributions to our board and to Clinuvel over more than 17 years".
Clinuvel fell 10 cents or 0.7 percent to $14.72.