Biotech Daily

Friday April 8, 2022

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.47 percent on Friday April 8, 2022, with the ASX200 up 35.2 points to 7,478.0 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and two were untraded.

Amplia was the best, up one cent or 7.1 percent to 15 cents, with 18,965 shares traded. Kazia and Orthocell climbed more than six percent; both Micro-X and Proteomics improved 4.55 percent; Genetic Signatures and Starpharma were up more than three percent; Alcidion and Oncosil rose more than two percent; Nanosonics, Paradigm, Pharmaxis, Pro Medicus, Resmed, Universal Biosensors and Volpara were up more than one percent; with Cochlear and Mesoblast up by less than one percent.

Impedimed led the falls for the second day in a row, down one cent or 7.7 percent to 12 cents, with 4.9 million shares traded. Both Antisense and Patrys fell 4.2 percent; Avita and Prescient were down more than three percent; Atomo and Opthea shed more than two percent; Polynovo and Telix were down more than one percent; with CSL, Medical Developments and Neuren down less than one percent.

DR BOREHAM'S CRUCIBLE: MICROBA LIFE SCIENCES

By TIM BOREHAM

ASX Code: MAP

Share price: 39.5 cents; **Shares on issue:** 274,357,998***; Market cap:** $108.4 million

***** 66,666,666 were issued in the initial public offer; 159,978,321 shares are in ASX escrow

Chief executive officer: Dr Luke Reid

Board: Pasquale Rombola (chair), Prof Ian Frazer, Prof Gene Tyson, Dr Caroline Popper, Dr Hyungtae Kim, Richard Bund

Financials (first half to December 2021): revenue $2.2 million, net loss $6.03 million, gross profit $1.17 million, cash $10 million

Major shareholders: SA Microbe Holdings (Mr Bund) 11.5%, Alium Alpha Fund (Dempsey Capital) 7.24%, Macrogen Inc 6.5%, Boysenholtz Pty Ltd 6.2%, Genenika Pty Ltd (Tyson Trust) 6.23%, Gingko Bioworks Inc 4%, Tiga Trading 2.67%.

It's easy to get the impression that the bloke upstairs is trying to knock us all off - one way or the other.

Following the pandemic, gastroenteritis has made a strong comeback as we discard masks and return to normal socialization.

While we'll be hearing more about nasty tummy bugs - usually from victims staying close to a bucket - spare a thought for the trillions of good 'germs' that inhabit the large intestine.

These bodily warriors help digestion and perform other crucial tasks. When harnessed, they can treat inflammatory and immune disorders.

That's the selling point of Microba, which listed on Tuesday on the back of its tests enabling consumers, clinicians and researchers to measure the gut microbiome.

As well as moderating disease and digestion, the clever bugs produce neuro-transmitters that can affect the brain, as well as metabolites that work systemically thought the body and impact various organs and systems.

"The big finding over the last decade has been that we have gone from 'any bug is a bad bug to be wiped out with antibiotics' to understanding the intimate relationship between these organisms and our health," says Microba CEO Luke Reid.

Central to Microba's story is a large databank of microbiomes, which the company has accumulated over the last four years. This depository is helping the company to develop therapies for chronic conditions such as inflammatory bowel disease (IBD), which affects more than six million people.

Microba under the microscope

Microba was formed in 2017 based on intellectual property acquired from the University of Queensland.

Also involved were the University of California Berkeley, Massachusetts Institute of Technology and the Joint Genome Institute.

Having attempted an initial public offer (IPO) two years ago, Microba listed on April 5 after raising $30 million at 45 cents apiece.

Microba's tech was developed by co-founders Prof Philip Hugenholtz and Prof Gene Tyson. The latter is an executive director and the former chairs its scientific advisory board.

With a PhD in molecular biology, CEO Luke Reid has a research and commercialization background. He was an associate director of Uniquest Pty Ltd and, before that, held roles at plant geneticist Dupont Pioneer.

Dr Reid met the two professors at Uniquest while working on unrelated tech and the rest - as they say - is history.

The company launched its first product, Microba Insight, in Australia in July 2018.

In 2019, it followed up with a gut microbiome measuring product, Metabiome, for healthcare professionals in Australia and New Zealand through a distribution partnership.

The company's deputy chair, Prof Ian Frazer needs no introduction as the co-inventor of the Gardasil and Cervarix cervical cancer vaccines.

The guts of the company

Microba has three arms: microbiome services (testing), drug development and a proprietary database of 1.2 million microbial genomes covering 5,000 species. The last will enable the company to "identify novel and therapeutic leads not identified by others".

To date, Microba has sold more than 20,000 microbiome test reports.

Consumers buy the test online and send back a stool sample, for which they receive a summary of their gut microbiome. Users outside a healthy range are provided with dietary recommendations or access to an accredited dietician.

Microba has rolled out the tests via distribution partners: Metagenics in Australia, Psomagen in the US and Europe's biggest pathology company, the German-listed Synlab.

Microba is about to launch a testing partnership with Genova Diagnostics in the US and has just signed a Middle Eastern compact with artificial intelligence outfit G42.

The company is also signing new partnerships in Japan, the UK and Taiwan.

Dr Reid describes the distribution model as “very high margin and very scalable”.

In effect, he says, Microba is the “Intel chip”. This means the company delivers the raw data and the tech to deliver a useful report. The partners do the sales, marketing, distribution and processing.

On the therapeutic side, the inflammatory bowel disease trial is due to start in late 2022.

Other potential targets are colon cancer, diabetes, non-alcoholic steato-hepatitis (Nash), Alzheimer’s disease, rheumatoid arthritis, anxiety and depression.

Microba has an agreement with the Bill Gates-backed, New York-listed Ginkgo Bioworks to address three autoimmune conditions.

Getting to the bottom of it

Squeamish folk should look away now, because the first proof-of-concept of the healing power of gut bugs involved a faecal microbiome transplant. As the name suggests, this involved anally injecting the poo of healthy donors into diseased patients.

Not surprisingly, several parties have tried to dignify the process by freeze drying the faeces and encapsulating the material.

But Dr Reid says there are “significant manufacturing challenges” in the process.

“They are acting blindly because they are not sure if the organisms work,” he says. “Microba is third generation in that we hone-in on key organisms and develop single strain monoclonal therapeutics.”

This means the therapies can be more readily manufactured and scaled up in a high-dose format.

In the clinic

The first clinical cab - or Uber - off the rank is an upcoming trial for mild to moderate ulcerative colitis. The company has chosen this one because there’s a significant unmet need, with patients suffering frequent flare-ups.

“Most of the [existing] drugs can only treat the downstream inflammation, they are not getting to the core of the disease,” Dr Reid says. “We have discovered a key organism that not only deals with inflammation, but promotes activity in epithelial restitution [wound healing of the ulceration in the gut].”

Due to kick off in December, a phase Ib trial will enrol 20 to 30 patients in two parts (healthy and diseased).

While Microba's key focus is on inflammatory bowel disease (IBD), the company is also interested in immune-oncology: enhancing the effectiveness of checkpoint inhibitors such as Keytruda.

Dr Reid says this drug class is great when it works, but 70 percent of patients don't respond. Big pharma is trying to work out why and a key factor is the gut microbiome.

Microba is doing a large study with cancer centres across the US and Australia, to identify the key organisms that identify the responders and non-responders.

Other studies have shown that if the faeces of a responder are implanted into a non-responder, the latter becomes responsive because of the altered microbiome. The trouble is, this method is not scaleable. Oh, poo!

Finances and performance

The IPO ascribed an initial market capitalization of $123 million, with the shares issued at 45 cents apiece. The first day was a bit of a fizzer, with the shares trading between 34 cents and 44 cents.

Microba chalked up $2.2 million in the first (December) half-year, which derived from selling testing services to consumers, healthcare practitioners and research entities (such as biotech and food companies).

The IPO was not general, meaning it was covered by existing shareholders and new institutions and high net worth individuals.

The fund managers on board include the Sydney's Alium and Melbourne's ubiquitous Thorney Investments. Gingko has a four percent holding and is also entitled to a $US3.5 million ($A4.6 million) research and development fee, payable in Microba shares or cash, 15 to 24 months after the IPO.

The company plans to use the $30 million raised on drug research ($13 million), sales growth via partnerships ($7.2 million), platform technology ($2.5 million) and working capital ($2.5 million).

The lowdown on probiotics

Microba's work is more than relevant to the trendy field of probiotics: micro-organisms that are claimed to benefit the gut when ingested.

Probiotics fall into the 'generally recognized as safe' category. In other words, they will not kill you, but may not necessarily benefit you.

Most consumers would be unaware that probiotics aren't one of the naturally occurring gut bugs: typically, they derive from dairy sources such as cheese, milk and yoghurt.

Dr Reid dubs the booming sector as ripe for disruption, given the poor disclosure and lack of clinical evidence to support the loose ‘health and wellness’ claims.

“We believe the next wave of evidence-based probiotics will be the organisms that naturally are part of the adult human gut,” Dr Reid says.

Probiotics aren’t sourced from the natural gut microbiome because exogenous sources can tolerate oxygen and are thus easier to make.

Human gut bugs need to be grown in low to zero oxygen conditions and manufacturing techniques to enable this are only just emerging.

“About 70 percent of the gut microbiome has not been brought into human culture in a lab,” Dr Reid says. “That’s a really important step that’s been a barrier for producing registered therapeutics and we have been able to overcome that.”

Dr Boreham’s diagnosis:

Ubiquitous research house Frost and Sullivan estimates the size of the microbiome testing market at $US4.89 billion and forecasts it to grow to $US6.7 billion by 2023, a compound annual rate of 7.5 percent.

“But we increasingly are seeing more players come into the market,” Dr Reid says.

“Everyone wants to jump in and take a piece of it. It will come down to the best technology and execution and that’s where I believe we have a significant edge.”

Ultimately, Microba expects to be taken over by big pharma or enter a partnering deal: the prospectus lists recent transactions between $US500 million and $US1.5 billion for early-stage plays.

A potential share price catalyst is US Food and Drug Administration approval of what would be the first microbiome-based therapy, for recurrent Clostridium difficile (a germ that causes colon inflammation).

This proposed drug has passed phase III testing by Seres Therapeutics and Ferring Pharmaceuticals.

Ultimately, Dr Reid expects microbiome testing to become as routine as blood testing and treat a range of inflammatory and mental health disorders.

Of course, Keytruda’s owner Merck would be salivating if checkpoint inhibitors could be made to be more effective.

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Next time he wants to skive off work with a tummy bug, he’ll tell his boss there’s a trillion reasons why.

PRO MEDICUS

Pro Medicus says wholly owned US subsidiary Visage Imaging has signed a $32 million, eight-year imaging contract with Inova Health System.

Pro Medicus said that the non-profit Falls Church, Virginia-based Inova contract would follow a transactional licencing model, with the company's Visage 7 enterprise imaging platform being implemented throughout Inova and Fairfax Radiology, a radiology organization jointly owned by Inova.

The company said planning for the rollout of the internet 'cloud' based system would begin immediately, with early-stage functionality targeted by the end of 2022.

Pro Medicus said Inova's more than 20,000 team members saw more than two million patient visits a year through a network of hospitals, primary and specialty care practices, emergency and urgent care centres, outpatient services and destination institutes.

The company said that Visage 7 would provide a cloud-based, unified diagnostic imaging platform across both networks, and that Inova was part of a growing trend among its clients towards cloud-based products.

Pro Medicus chief executive officer Dr Sam Hupert said the Inova deal was "our fourth major contract in the [integrated delivery network] space in less than 18 months, which further underpins the strong momentum we continue to build not only in this segment of the market but also the North American market as a whole."

"Our pipeline remains strong," Dr Hupert said. "Deals like this confirm our view that Visage 7, with its proven cloud-native technology provides us with a significant strategic advantage that addresses these opportunities across a growing segment of the market both in North America and other regions."

Pro Medicus was up 77 cents or 1.6 percent to $47.97 with 150,300 shares traded.

RHINOMED

Rhinomed says it has completed a $3.37 million placement at 19 cents a share, and hopes to raise a further $1.63 million in a retail rights offer at the same price.

Yesterday, Rhinomed said the offer price was a 7.3 percent discount to its previous closing price (BD: Apr 7, 2022).

Rhinomed was in a trading halt at 20.5 cents.

PHARMAUST

Pharmaust says it has received $201,615 for its phase I trial of monepantel in motor neuron disease, and has appointed Alithia Life Sciences Pty Ltd as the trial manager.

In 2020, Pharmaust said it had received an $881,085 grant for a phase I trial of monepantel for motor neuron disease from the charity Fight MND (BD: Sep 21, 2020).

Today, the company said the $201,615 was the first instalment of the Fight MND grant supporting its phase I trial examining the effects of monepantel in motor neuron disease otherwise known as Lou Gehrig Syndrome or Amyotrophic Lateral Sclerosis.

Pharmaust said the second instalment of $99,230 would be payable after the completion of the one-month good manufacturing practice accelerated stability study of the newly-prepared monepantel tablets, which was currently underway, and the third instalment of $173,035 would be payable on the start of the phase I trial.

Separately, the company said that Melbourne's Alithia would manage the phase I trial and the appointment was fully funded through the Fight MND grant.

The company said its trial start date of late May remained on track.

Pharmaust was up 0.3 cents or 3.4 percent to 9.2 cents.

KAZIA THERAPEUTICS

Kazia says pre-clinical data shows its Paxalisib is active in two forms of childhood brain cancer with high unmet need.

Kazia said three abstracts from researchers at the Baltimore, Maryland-based Johns Hopkins University would be presented at the American Association for Cancer Research meeting in New Orleans, from April 8 to 13, 2022.

The company said that two abstracts described the use of paxalisib "as a backbone therapy in a childhood brain cancer known as atypical teratoid-rhabdoid tumors".

Kazia said it was the first time that data exploring paxalisib in atypical teratoid-rhabdoid tumors had been presented, opening "an important new potential indication for the drug".

The company said the two abstracts were titled: 'The PI3K inhibitor Paxalisib combines with the novel HDAC1/3 inhibitor RG2833 to improve survival in mice bearing orthotopic xenografts of atypical teratoid-rhabdoid tumors';

and 'The PI3K inhibitor Paxalisib combines synergistically with the pan-Raf inhibitor TAK580 (DAY 101) to extend survival in orthotopic xenograft models of atypical teratoid-rhabdoid tumors'.

Kazia said a third abstract showed evidence of "strong synergy between paxalisib and another class of cancer therapies in a model of diffuse intrinsic pontine glioma (DIPG)".

The company said that paxalisib had previously shown evidence of activity in diffuse intrinsic pontine glioma, both as monotherapy and in combination with several types of cancer therapy, and the new data further validated its potential in the disease.

Kazia said the abstract was titled 'Brain penetrant HDAC and PI3K/mTOR inhibitors synergize to induce DIPG cell death'.

Kazia chief executive officer Dr James Garner said that this was "very promising data, and we are grateful to the team at Johns Hopkins for this important and encouraging research".

"Paxalisib is already the subject of an ongoing phase II clinical trial in [diffuse intrinsic pontine glioma] and diffuse midline gliomas and this new data suggests potential wider applications for the drug in childhood brain cancers," Dr Garner said.

Kazia was up 6.5 cents or 6.05 percent to $1.14.

IMRICOR MEDICAL SYSTEMS

Imricor says it proposes to issue $US288,819 ($A386,122) worth of options to its chief executive officer, and $US111,250 ($A148,786) in restricted stock to three directors.

Imricor said its annual general meeting would vote to issue 1,272,891 options in three tranches, exercisable at 22.69 US cents each, worth $US288,819 ($A386,122), to chief executive officer Steve Wedan.

The company said that "in lieu of a higher cash remuneration" the meeting would vote to issue 107,253 restricted stock, worth US$40,000 each, to directors Peter McGregor and Mark Tibbles; and 83,791 restricted stock, worth US$31,250, to Anita Messal.

Imricor said the restricted stock awards would vest in four equal tranches.

The company said share-holders would vote on the election of Mr McGregor as a director, the ratification and approval of prior issue of Chess depositary instruments under a September placement, and a 10 percent placement facility.

Imricor said that the virtual meeting would be held on May 4, 2022 at 9am (AEST),

Imricor fell 2.5 cents or four percent to 60 cents.

CORRECTION: EMYRIA

A headline in last night's edition incorrectly said that Emyria's phase I trial was for epilepsy; the article was correct as published.

While Emyria's 150mg EMD-RX5 cannabidiol (CBD) capsules will be compared with the anti-epilepsy drug 100mg/ml Epidyolex CBD, the trial is a safety, tolerability and bio-availability study.

Emyria has told Biotech Daily that it is not pursuing an epilepsy indication and its initial target indication is psychological distress - a schedule 3 over-the-counter indication, with plans for an irritable bowel disorder indication.

The Thursday sub-editor has been suitably admonished for carelessness and despatched to Manhattan's Andy Warhol University to undertake a course in Less Is More 101.

Emyria was up one cent or 3.3 percent to 31.5 cents.

ARTRYA

Artrya says that 5,776,095 shares will be released from ASX escrow, with 5,183,961 shares to be released on April 19 and 592,134 shares to be released on April 23, 2022.

Artrya said that following the release of the shares, it would have 62,637,120 shares available for trading, with a further 15,610,470 shares held in ASX escrow until November 26, 2023 and 25,168,121 shares held in voluntary escrow until November 26, 2022.

Artrya fell five cents or 4.55 percent to $1.05.

NANOSONICS

State Street says it has reduced its substantial holding in Nanosonics from 20,774,549 shares (6.88%) to 17,652,342 shares (5.85%).

The Boston-based State Street said that in more than 150 transactions between March 9 and April 6, 2022, it bought sold, borrowed and transferred at prices ranging from $3.82 to $4.00.

Nanosonics was up four cents or one percent to $3.96 with 472,510 shares traded.