Biotech Daily

Friday October 7, 2022

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.8 percent on Friday October 7, with the ASX200 down 54.7 points to 6,762.8 points. Fourteen of the Biotech Daily Top 40 companies were up, 19 fell, four traded unchanged and three were untraded. All three Big Caps fell.

Oncosil was the best, up 0.65 cents or 15.5 percent to 4.85 cents, with 1.4 million shares traded. Dimerix climbed 10 percent; Mesoblast was up six percent; Atomo and Resonance were up five percent or more; Immutep improved 3.85 percent; Compumedics and Imugene rose more than two percent; Cynata, Medical Developments and Orthocell were up more than one percent; with Neuren, Opthea and Volpara up by less than one percent.

Uscom led the falls, down 1.3 cents or 16.7 percent to 6.5 cents, with 278,360 shares traded. Paradigm lost 13.2 percent; Starpharma fell 10.3 percent; Kazia was down 7.9 percent; Next Science lost 6.25 percent; Patrys fell five percent; Amplia fell 4.8 percent; Micro-X, Polynovo, Telix and Universal Biosensors were down more than three percent; Clinuvel, Cyclopharm and Nanosonics shed more than two percent; Avita, Cochlear, Impedimed, Pharmaxis and Pro Medicus were down one percent or more; with CSL, Proteomics and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: GENETIC SIGNATURES

By TIM BOREHAM

ASX code: GSS

Share price: 81.5 cents; **Shares on issue:** 143,385,996; **Market cap:** $116.9 million

Chief executive officer: Dr John Melki

Board: Dr Nick Samaras (chair), Dr Melki, Dr Tony Radford, Michael Aicher (US executive director), Dr Neil Gunn, Caroline Waldron

Financials (12 months to June 30 2022): revenue $35.4 million (up 25%), net profit $3.06 million (up 74%), net tangible assets per share 37 cents (up 8%), cash on hand $36.8 million (up 22%)

June quarter 2022: sales $4.9 million, cash outflows $169,000, quarters of available funding: 218

Identifiable major holders: Christopher Abbott (Asia Union Investments) 26%, Perennial Value Management 15%, Fidelity Investments 6.9%

As Maxwell Smart once said: "missed it by that much".

In Genetic Signatures' case, the close-but-no-cigar moment was its narrow June quarter loss of $169,000, which meant the company did not achieve four consecutive quarters of cash flow positive results.

If it had done so, it would no longer have been required to lodge quarterly reports to the ASX.

"I was quite disappointed," says chief finance officer Peter Manley. "One [customer] payment arrived on the second of July, which might have got us there."

Mr Manley notes that most of the cash outflows pertained to the molecular diagnostic outfit's investments in new customer sites, so it was 'good' spending.

Genetic Signatures also reported record revenue for the year to June 2022, but the reality is the company is exiting pandemic-era demand for its proprietary molecular testing products that enable faster and more accurate assays.

"We were early [with Covid testing] and we did well. Other companies thought it was like Sars [severe acute respiratory syndrome] and would go away," says chief executive Dr John Melki.

Now, the molecular polymerase chain reaction testing has been replaced by the less reliable rapid antigen tests. And governments are eschewing mask mandates and compulsory as quickly as you can say 're election'.

The genesis of Genetic Signatures

Genetic Signatures was founded in 2001 by prominent fund manager Christopher Abbott and the late Dr Geoffrey Grigg, former head of microbiology at the esteemed Commonwealth Scientific and Industrial Research Organisation (CSIRO).

The company's original focus was on commercializing technology using a sodium bisulphite conversion method which, it was discovered, could be used to develop molecular assays for infectious pathogens.

Genetic Signatures sprung from CSIRO's laboratories in Sydney's North Ryde.

Dr Melki joined the company in 2003, having researched DNA and microarray technologies.

Genetic Signatures listed on the ASX in March 2015, raising $7.5 million at 40 cents apiece.

The co-founder of boutique investment house Maple Brown Abbott, Christopher Abbott retains a 26 percent Genetic Signatures stake.

A company with all its (3) bases covered

While there are plenty of molecular diagnostic providers, Dr Melki says Genetic Signatures distinguishes itself with its ability to do syndromic (that is, multiple) tests.

Genetic Signatures' tests are based on its 3base platform, which can detect up to 20 organisms at a time from the one patient, thus shortening the wait time from days to hours.

Technically speaking, 3base converts the 4base microbial genome to three, with no additional steps required by the operator.

"3base allows us to detect the most common infectious agents with low-cost test kits," Dr Melki says.

In Europe, there's still a lot of gastro testing with agar plates, which means a four to five days turnaround - during which the patient has probably recovered anyway.

The kits can detect more than 150 diseases across five broad categories: enteric (intestinal), respiratory, antimicrobial resistance, fungal and sexually transmitted infections (which spiked post lockdowns as folk got - er - out and about).

One example in the enteric category is the gastro disease norovirus, the bane of cruise ships in pre-Covid times and no doubt the blight of seafarers as the floating germ palaces set sail again.

The tests also detect salmonella and giardia. In the respiratory space, the assays pick up influenza A and B as well as Sars-Cov-2 of course.

Commercialization to date

Sold under the Easyscreen banner, Genetic Signatures' tests were developed (and are made) in Australia, with sales in more than 30 countries but mainly on the company's home turf. More than two million patients have undergone at least one Easyscreen test.

The tests replace the old 'sample on a slide' laboratory methods, enabling rapid screening of pathogens so that the right antibiotics can be swiftly administered.

The company has approved tests for the enteric, respiratory and antimicrobial indications in Australia and Europe, while the latter has also approved sexually transmitted infections (STI) tests.

In April 2020, the company swiftly won consent to sell its Covid tests in Europe and Australia - and wasted no time shipping them.

An important feature of the Covid test is that it can distinguish between The Dreaded Plague - trade mark pending - and rhinovirus (a.k.a the common cold).

Dr Melki says Genetic Signatures is soundly positioned as authorities turn to the all-in-one testing approach.

For instance, the New South Wales Health Department is moving away from Covid tests to panel testing for Covid and influenzas A and B "at a minimum".

"We are in a position where we can convert the Covid 19 customers we have gained to full panel testing."

Finances and performance

Genetic Signatures revenue for the 2021-'22 year came in at $35.42 million, 25 percent higher. But reflecting the tougher post-Covid conditions, June quarter sales declined 22 percent to $4.9 million (year-on-year).

Despite the aforementioned June quarter loss, the company managed a $3.06 million profit for the year, up 74 percent.

Mr Manley notes that unlike for the year as a whole, in the June quarter non-Covid revenue was greater than Covid testing income. Barring a big new Covid screening program, that should continue to be the case.

The annual revenue derived 89 percent from the Asia Pacific - mainly Australia - and 11 percent from Europe.

Over the last 12 months Genetic Signatures shares have traded between $1.79 in late December 2021 and the late September 2022 low point of 82 cents.

Since listing Genetic Signatures shares have changed hands between 25 cents (March 2018) and $2.82 (July 27, 2020).

Looking for home ‘runs’ in the US

A key focus for Genetic Signatures is its US Food and Drug Administration (510k) submission for its enteric protozoan kits, which it hopes to lodge by the end of 2022. After Covid disruptions, the company managed to collect the requisite 1,500 samples to carry out the supportive trial (across three sites).

Found in the gut of humans and other mammals, enteric protozoa are diarrhoea-inducing parasitic infections including giardia and cryptosporidium. They are hard to detect with traditional methods and can cause chronic illness.

“Other tests will identify three to four of them, but Genetic Signatures’ tests can identify eight of these nasties at once, at least twice as many as rival kits,” Dr Melki says.

The company notes that about 5.5 million enteric protozoan tests are done in the US annually and the company aims for a 40 percent market share.

Thanks for the reimbursement

Handily, there’s already a requisite US reimbursement (insurance) code, allowing for $US262.99 per test. This compares with a payment “in the low tens” for microscopy tests.

For the labs, this means testing can change from being a cost to a profitable activity. Genetic Signatures won’t pocket all of the $US263, but can expect a handy margin. In the meantime, Australian molecular diagnostics reimbursement is a bit on the stingy side (our words): the going rate for a test targeting three or more diseases is a mere $32.

And seeing that you asked, in Wales, every suspected gastro case is subject to an Easyscreen test, generating $1.8 million of annual revenue for the company. Now that’s something to sing about!

Ticking the wrong box

Genetic Signatures this week was forced to admit to the ASX that an announcement on September 29 was inadvertently ticked as ‘market sensitive’.

The disclosure related to a publication in the peer review organ Journal Diagnostics, which referred to Easyscreen producing “excellent” results in testing for antimicrobial resistance.

Given the piece was published on September 14, the bourse wanted to know why the company took so long to ‘announce’ (our words) the epic news (still our words). The company found out about the news on September 23.

While regretting the error, the company noted that while the announcement wasn’t market sensitive it was still “relevant to shareholders given an independent entity had assessed one of the company’s products to be of sound quality”.

On behalf of the ASX, we consider the matter now closed.

Coming up …

While the tests themselves can work on any platform, the company also provides Easyscreen-specific instrumentation to laboratories with higher throughput.

Looking like a cross between a photocopier and a microwave, the units are available in three models of varying size and functionality.

The company is also working on a fully automated, next generation instrument for 3base assays. The device will combine extraction, analysis and recording in a single process "while maintaining throughput for multiple targets".

It's expected the machines will be available to laboratories on a reagent rental model (that is, free to the clients as long as they buy the consumables).

The company is also working on other indications including dermatophytes (fungus), tick-borne nasties (such as Lime disease), mosquito-borne tropical diseases and Japanese encephalitis (pronounced, by the way, with a hard 'c').

The company is also working with the FDA on a potential trial for a second test. Dr Melki says the trial will be easier to run than the enteric protozoan effort, because samples will be more readily available.

Dr Boreham's diagnosis:

In the words of Frank Sinatra, can the company just pick itself up and get back in the race, share price wise?

Much depends on the degree to which the company can replace Covid-related revenues from those deriving from the rest of the 150-plus pathogens which its Easyscreen tests can detect.

"The year ahead is going to be about investing in growth for the transition from Covid related business to the broader business," Mr Manley says.

The still-raging Covid aside, Genetic Signatures remains just as relevant in a diseased world - and we're talking literally as well as metaphorically.

Not surprisingly, management's focus is on building Europe and US revenues, given these geographies account for 70 percent of the global molecular testing market.

"Australia is one to two percent of the world market, so if we can replicate what we do in Australia over there, we are in clover," Dr Melki says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But rest assured, he treats his columns as more than a box-ticking exercise.

VICTORIA GOVERNMENT, BIONTECH

The Victorian Government says it has an in-principle partnership with the Mainz, Germany Biontech to establish an mRNA clinical research and development centre.

A media release from the Treasurer and Minister for Economic Development and Trade Tim Pallas said that Biontech had chosen Victoria for their Asia-Pacific development centre to "support researchers and translate their work into medical breakthroughs".

The media release said that Biontech was a leader in mRNA research and in 2020 successfully developed the Pfizer and Biontech vaccine against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

The Government said that Biontech would deliver next-generation mRNA therapeutics and vaccines for research and clinical trials, including infectious diseases, cancer medicines and personalized cancer treatments, as well as establishing its artificial intelligence-driven early warning and identification technology to detect future disease threats and new treatments and vaccines.

"This is a major coup for Victoria," Mr Pallas said. "It will see incredible collaboration opportunities for our researchers and international biotech companies."

Biontech chief executive officer and co-founder Prof Uĝur Şahin said "this partnership is a major step forward to enable access to mRNA technology and promote collaboration"

"Australia provides excellent academic research, and we are looking forward to collaborating with world-class scientists and researchers to strengthen Australia's mRNA ecosystem and jointly develop novel treatments and vaccines for people worldwide," Prof Şahin said.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that common liver diseases are not driven by inflammatory cell death as previously understood.

WEHI said the study used pre-clinical genetic models of liver diseases including non-alcoholic fatty liver disease and non-alcoholic steato-hepatitis, as well as hepatitis B, and deleted key genes, known as hepatocytes, required for necroptosis, an inflammatory form of cell death, from liver cells to observe the effects on disease development.

The Institute said that researchers found that deleting the genes had little effect, with disease progression proving comparable to normal hepatocytes, which showed that necroptosis was not involved in the development of these liver pathologies.

WEHI said that the study found that hepatocytes could not produce a protein essential for necroptosis, RIPK3, blocked by a type of epigenetic modification known as methylation which acts as a genetic blockade, preventing the body's protein production machinery from binding to the DNA and building RIPK3 protein.

The research article, titled 'Epigenetic silencing of RIPK3 in hepatocytes prevents MLKL-mediated necroptosis from contributing to liver pathologies' was published in Gastroenterology and is available at: https://doi.org/10.1053/j.gastro.2022.08.040 .

WEHI said that the research was led by Dr Marcel Doerflinger, Dr Simon Preston and Prof Marc Pellegrini in collaboration with researchers from the Peter Doherty Institute in Melbourne and the University of Queensland.

Dr Doerflinger said it was unclear why necroptosis was repressed in liver tissue, "but we speculate it may be because the liver is constantly bathed in necroptotic signals such as gut microbial products, so limiting necroptosis could potentially protect the liver from excessive inflammation".

"These findings are a central piece of data that address many unanswered questions … that will guide future pre-clinical trials and clinical studies," Dr Doerflinger said.

PRESCIENT THERAPEUTICS

Prescient Therapeutics says it raised $8.76 million in an oversubscribed share plan at 17.5 cent a share.
In August, Prescient said it hoped to raise $8 million in the share plan (BD: Aug 24, 2022).
Today, the company said it requested a trading halt "to allow wholesale shareholders who indicated interest throughout the [share plan] in funding applications greater than $30,000 to participate in a placement".
Prescient last traded at 18.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will launch the 'Wilam' platform for the life sciences community to come together in real time to discuss challenges and opportunities.
The Network said that Wilam meant "home" in the Woi-wurrung language of Wurundjeri People of the Kulin Nation, the traditional owners of Melbourne.
The Bio-Melbourne Network said that Wilam would be a database allowing businesses and individuals "to start conversations, share knowledge and connect and network with peers and potential partners".
Bio-Melbourne chief executive officer Jeff Malone said the life sciences industry was "strong but siloed … [and] missing out on opportunities to connect, collaborate and grow".
"Wilam is our contribution to solving this," Mr Malone said.
Mr Malone said the platform could be used by individuals and organizations "to come together in real-time to have real conversations".
"Through Wilam, the eco-system will connect, ask questions, access knowledge, network, and participate in community-led groups," Mr Malone said.
"It will function as a catalyst for the life sciences industry to network in ways that fully leverage the new technologies available," Mr Malone said.
"Wilam has discussion boards, tiered community and working groups, a searchable directory, library, and an events calendar," Mr Malone said. "It brings all the information, events, questions, and resources that you're interested in, to you."
Wilam will be launched this month and to preview the platform, go to: www.wilam.com.

CLARITY PHARMACEUTICALS

Clarity says it has treated the first of up to 30 patients in its 'Secure' phase II trial of 67-copper sarcophagine (Sar)-BIS-PSMA for prostate cancer.
Last month, Clarity said it had imaged the first patients in the trial (BD: Sep 14, 2022).
Today, Clarity said it had dosed the first patient in the therapeutic phase of the trial at the GU Research Network's Urology Cancer Center in Omaha, Nebraska.
The trials principal investigator Dr Luke Nordquist said the group was "excited" to treat the first patient with 67-copper Sar-BIS-prostate-specific membrane antigen (PSMA).
"The pre-clinical and preliminary clinical data to date indicates potential diagnostic and therapeutic benefits of the optimized PSMA agent," Dr Nordquist said.
He said that the GU Research Network was recruiting patients in three clinical trials with Clarity's copper radiopharmaceutical agents.
"This next-generation platform will help to overcome the logistical and manufacturing challenges that currently plague the radio-pharmaceutical field," Dr Nordquist said. "This way, the clinicians can focus on providing the best patient care without the fear of reactor shutdowns or manufacturing outages disrupting the treatment process."
Clarity fell one cent or 1.6 percent to 60.5 cents.

ROYAL MELBOURNE INSTITUTE OF TECHNOLOGY

Royal Melbourne Institute of Technology says a voice screening application could help detect Parkinson's disease and severe Covid-19 early in 10 seconds.

RMIT said that a screening test using artificial intelligence could produce accurate results for detecting Parkinson's disease and Covid-19 using people's voice recordings.

The Institute said that Parkinson's disease was diagnosed through an evaluation with a neurologist that could take up to 90 minutes, but the application took 10 seconds to show whether they might have Parkinson's disease and should be referred to a neurologist.

RMIT said that a similar test was developed for people with Covid-19 to determine if they needed clinical attention.

RMIT lead researcher Prof Dinesh Kumar said that early detection, diagnosis and treatment "could help manage these illnesses, and so making screening faster and more accessible is critical".

"This research will allow a non-contact, easy-to-use and low-cost test that can be performed routinely anywhere in the world, where the clinicians can monitor their patients remotely," Prof Kumar said.

"It could also promote a community-wide screening program, reaching people who might not otherwise seek treatment until it's too late," Prof Kumar said.

RMIT said that the voice of people with Parkinson's disease changes because of a combination of three symptoms: rigidity, tremor and slowness, or bradykinesia.

Prof Kumar said previous attempts to develop a computerized voice test to detect Parkinson's had been inaccurate due to significant differences in people's voices.

"As part of our research, we used voice recordings of people with Parkinson's and a controlled group of so-called healthy people saying three sounds: A, O and M, which is similar to the Hindu meditation chant," Prof Kumar said.

"These sounds result in a more accurate detection of the disease [and] in patients with pulmonary disease symptoms from Covid-19, there is also a change in the voice due to lung infection," Prof Kumar said.

"Again, due to large differences in people's voices, pulmonary disease is difficult to recognise in its early stages," Prof Kumar said.

"We have overcome this limitation with the choice of those same three sounds and the [artificial intelligence] method of analysis we've developed," Prof Kumar said.

RMIT said that prior to being used, the system was trained to identify the disease and once trained, it performed "an instantaneous analysis of the voice" and then compared the results against samples of voices of people with Parkinson's and healthy voices.

RMIT said the study, tilted 'Voice Features of Sustained Phoneme as COVID-19 Biomarker' was published in the IEEE Journal of Translational Engineering in Health and Medicine and was available at: https://ieeexplore.ieee.org/document/9895437.

The Institute said that a second study, titled ''Parkinson's Disease Detection Using Smartphone Recorded Phonemes in Real World Conditions' was published in IEEE Access and was available at: https://ieeexplore.ieee.org/document/9887934/.

A third study, titled 'Convolutional neural network ensemble for Parkinson's disease detection from voice recordings' was published in Computers in Biology and Medicine and was at: https://www.sciencedirect.com/science/article/pii/S0010482521008155.

RMIT co-researcher Dr Quoc Cuong Ngo said "our screening test [application] can measure, with great precision, how the voice of someone with Parkinson's disease or person at high risk of hospitalization from Covid-19 is different from healthy people".

RMIT said the team wanted to perform a larger observational study to detect the progression of the Parkinson's and pulmonary diseases and was "looking for a commercial partner and clinical partner ahead of a clinical trial planned for next year".

CARTHERICS

Cartherics says the US Patent and Trademark Office has granted a patent protecting its chimeric antigen receptor T-cell and stem cell-based technology.
Cartherics said the patent, titled 'Genetically modified cells and uses thereof' would protect the technology until 2036.
Cartherics is a private company.

IMMUTEP

Immutep says it will present two abstracts on its IMP321, or eftilagimod alpha, at the Society for Immunotherapy of Cancer Boston meeting, from November 8 to 12, 2022.
Immutep said the abstracts were titled; 'Feasibility of eftilagimod alpha (soluble LAG-3 protein) combined with standard-of-care-therapy in advanced non-small-cell lung cancer (NSCLC) adenocarcinomas. Initial results from Insight 003' and 'TACTI-003: A randomized phase IIb study of eftilagimod alpha (soluble LAG-3 protein) and pembrolizumab as first-line treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma'.
Immutep was up one cent or 3.85 percent to 27 cents.

IMUGENE

Imugene says it will present three abstracts on its Oncarlytics oncolytic virus at the Society for Immunotherapy of Cancer Boston meeting, from November 8 to 12, 2022.
Imugene said that the abstracts were titled; 'Combination immunotherapy using a novel chimeric oncolytic virus to redirect CD19 bispecific T-cell engagers to target solid tumors'; 'CF33-CD19t oncolytic virus (Oncarlytics) targets hepatocellular carcinoma (HCC) and in combination with Artemis CD19 T-cells results in significant tumor killing'; and 'CF33-CD19t oncolytic virus (Oncarlytics) in combination with off-the-shelf allogeneic CyCART-19 T-cells targeting de-novo CD19+ solid tumors'.
Imugene was up half a cent or 2.6 percent to 19.5 cents with 14.2 million shares traded.

NUHEARA

The ASX says Nuheara has been reinstated to quotation following lodgment of its annual report and appendix 4G.
Yesterday, Nuheara said it had lodged both documents on the ASX.
On Monday, the ASX said that Nuheara had been suspended for failing to file the financial reports (BD: Oct 3, 2022).
Nuheara fell two cents or 9.5 percent to 19 cents.

MICRO-X

Micro-X says that non-executive director Yasmin King has resigned, effective from today.
Micro-X managing-director Peter Rowland said he had worked with Ms King as a director for nearly six years and "would like to acknowledge and thank her for her strong contribution through these critical, early growth years of our company".
"Yasmin also played a lead role in our shift to in-source [carbon nanotube] emitter and tube technology in 2018 which has become the cornerstone platform of our four-product strategy," Mr Rowland said.
Micro-X fell half a cent or 3.45 percent to 14 cents.

ARTRYA

Artrya says it has appointed Kevin Hart to replace company secretary Nathan Bartrop.
Artrya said both Mr Hart and Mr Bartrop worked for Perth's Endeavour Corporate, an advisory firm that provides company secretarial and accounting services.
Artrya was unchanged at 61 cents.