



Biotech Daily

Friday March 6, 2020

Daily news on ASX-listed biotechnology companies

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- * **ESENSE-LAB: ITZIK MIZRAHI CEO ON \$236k, JAMES BAHEN CO SEC**

MARKET REPORT

The Australian stock market tumbled 2.8 percent on Friday March 6, 2020, with the ASX200 down 179.5 points to 6,216.2 points. Six of the Biotech Daily Top 40 stocks were up, 31 fell, two traded unchanged and one was untraded. All three Big Caps fell.

Universal Biosensors was the best, up 3.5 cents or 21.9 percent to 19.5 cents with 1.1 million shares traded. Oncosil climbed 8.7 percent; Patrys was up 6.25 percent; Clinuvel improved 5.1 percent; LBT rose 4.55 percent; with Genetic Signatures up 2.4 percent.

Alterity (Prana) led the falls, down 0.3 cents or 18.75 percent to 1.3 cents, with 346,025 shares traded. Impedimed lost 14.9 percent; Actinogen and Uscom shed 12 percent or more; Avita and Osprey fell more than 11 percent; Compumedics and Next Science were down more than seven percent; Resonance retreated 6.45 percent; Amplia, Antisense, Cynata, Mesoblast and Neuren were down more than five percent; Immutep, Imugene, Paradigm, Pharmaxis, Polynovo, Proteomics and Telix fell four percent or more; Dimerix, Nanosonics, Opthea, Orthocell, Resmed and Volpara were down more than three percent; Cochlear, Ellex, Pro Medicus, Prescient and Starpharma shed two percent or more; with CSL and Medical Developments down by less than one percent.

[DR BOREHAM'S CRUCIBLE: CORONAVIRUS SPECIAL](#)

By **TIM BOREHAM**

Biotron (BIT)
Uscom (UCM)
Genetic Signatures (GSS)
Micro-X (MX1)
Zoono (ZNO)
Eagle Health (EHH)
Aeris Environmental (AEI)
Food Revolution (FOD)
IDT Australia (IDT)

As with the early medical cannabis plays, a cluster of ASX-listed stocks has wasted little time attaching itself to the 'c' word.

We're talking of course about the coronavirus Covid-19 but not sadly another 'c' word: cure.

Or not yet.

According to broker Morgans' daily tally, the virulent bug has so far infected 95,332 people, with 38,564 current cases (6,883 of them critical).

Of the remaining 56,768 cases with an "outcome", 53,483 recovered and 6,883 achieved a definitive performance indicator. They died.

Okay, a circa seven percent mortality rate - or even a one or two percent rate - is nothing to sneeze at, so to speak. But we do wish breathless TV reporters would cease referring to it as the "deadly" virus, but that would be like asking them to stop referring to a "horror smash" rather than a sad everyday road accident.

While we're on it, we also implore folk to stop hoarding toilet paper: after all, it's the coronavirus, not the Caroma-virus.

Named after its crown-like shape but not the Royal Family per se, the common coronavirus is responsible for past pestilences including Severe Acute Respiratory Syndrome (SARS) and Middle Eastern Respiratory Syndrome (MERS).

The virus may indeed fizzle out, as the earlier SARS plague did.

But for the time being, we need the best and brightest minds in the labs to come up with a treatment or - more likely - a vaccine.

There are some promising developments overseas, which your columnist will return to if he hasn't succumbed as well (he did shake hands with someone who went to a Chinese restaurant a couple of weeks back).

Biotron

Among the local biotechs - and we use the term loosely - there's been no lack of endeavor in linking their efforts to the virus. But to be fair, in some cases investors did it for them.

Take Biotron, which was an obvious subject of attention given the company is focused on developing antiviral drugs for HIV and hepatitis.

Biotron also has a program for pan respiratory viruses and mentioned "corona" in a June 2019 presentation. Some punters latched on to the fact that it wasn't referring to a 1970s Toyota or Mexican beer and the Hot Copper pundits were off and running.

Biotron CEO Dr Michelle Miller has been more circumspect.

Yes, she says, the company has some "good advanced compounds" to work on, but the reality is that there's nothing that would be ready to fight the current outbreak. Dr Miller says while the company's work on pan respiratory viruses continues, but there's not much to add at this stage.

Uscom

Uscom shares went on a run after the company reported increased orders for its haemodynamic monitoring devices in China.

Uscom stands for Ultra-Sonic Cardiac Output Monitors. The Uscom 1A device is a non-invasive diagnostic that monitors cardiovascular functions, using Doppler ultrasound to detect abnormalities.

Chinese health authorities have recommended Uscom 1A as a monitoring device for severe coronavirus cases, while international guidelines also suggest using the device for paediatric sepsis.

Uscom reported that in the first five weeks of 2019, Chinese sales orders rose 124 percent, from 17 units to 38 units.

Uscom chief Prof Rob Phillips says the company is "well positioned" with the virus, but notes that Uscom is not a coronavirus story as such: fatalities result from cardiovascular pulmonary failure from conditions such as pneumonia.

Happily for Uscom, the outbreak comes as the company hones-in on the Chinese market with a new direct sales model.

Genetic Signatures

The molecular diagnostics house has a suite of approved tests that cover gastro-enteric strains, flavivirus/alphavirus, sexually-transmitted diseases and - drum roll - respiratory pathogens.

Genetic's Easyscreen tests cover 'pan coronaviruses', which until now, has not been able to distinguish Covid-19 from, say, SARS.

But that's all changed, with the company introducing a supplementary test that does just that. Management is fast-tracking a validation program "to obtain the data required for international regulatory approvals as rapidly as possible".

However, Genetic Signatures can't be accused of beating up its prospects: management says while the bug presents "significant opportunities, the outcome of the emerging pandemic is uncertain".

Micro-X

While the early-stage coronavirus is detected by a blood test, chest x-rays are then used to gauge the severity of the illness and assess fluid in the lungs

Micro-X is all about developing lightweight and portable x-ray machines for medical applications, as well as other purposes such as defence and airports. The company's first product, Carestream DRX Revolution Nano is approved in the US and Europe.

In mid-February the company said it had procured orders for \$780,000 of machines from governments of two Asian countries, in response to the coronavirus threat.

This week, another \$1 million of orders - all marked 'for urgent delivery' - flooded in.

"While these are terrible circumstances with the coronavirus spreading so quickly, we are pleased that our equipment will soon be able to assist medical teams with their responses in affected countries," Micro-X CEO Peter Rowland says.

Sanitizers or soap?

Why waste a crisis? No fewer than four ASX stocks are capitalizing on demand for hand and surface sanitizers to halt the bug in the first place.

'Antimicrobial solutions' house **Zoono Group** proclaims its impressively-monikered Z-71 Microbe Shield - as used in its hand sanitizers - kills Covid-19 99.99 percent of the time.

Zoono is selling into China via a tie up with Eagle Health, which manufactures and distributes product into 26 provinces.

Aeris Environment goes one step better, claiming its Aeris Active product kills influenza and noroviruses in 99.999 percent of cases.

For those the remaining 0.001 percent, bad luck - and don't buy a lottery ticket.

Interestingly, that announcement did not refer specifically to the coronavirus. But earlier Aeris announced the Singapore National Environment Agency had listed Aeris Active as one of the "general disinfectants" effective against the virus.

Meanwhile, fruit juice maker **Food Revolution Group** has turned from filling its bottles with squeezed oranges to stuffing them with alcohol-based hand sanitizer under the Sanicare brand.

Who would have thought? The swift repositioning results from a 1,260 square metre upgrade at the company's plant at Mill Park in outer Melbourne, which enables all sorts of gels, powders, oils and cosmetics to be bottled.

Mainstream sanitizer products such as Dettol and Lysol (made by multinational Reckitt and Benckiser) are flying off the shelves.

But is a good scrub with soap and water just as effective?

Australian National University microbiologist Prof Peter Collignon opines there's little difference between hand washing and the alcohol-based sanitizers.

"One is just more convenient than the other and contains alcohol," he says. "You can put it in your pocket and don't have to be near a sink or basin to use it."

The quest for a 'cure'

So ... who's actually tackling the disease? Offshore, there's a conga line of developers having a crack at a vaccine.

In Israel, scientists at the **Galilee Research Institute** claim to be on the cusp of finalizing a product that is capable of getting regulatory assent within 90 days.

That's what you call fast-track approval.

According to the Jerusalem Post, the same team of scientists has been developing a prophylactic against infectious bronchitis virus, which affects poultry.

The effectiveness of the vaccine has been proven in pre-clinical trials carried out at the country's Veterinary Institute.

In the US, **Gilead Sciences** plans to recruit 1,000 patients with coronavirus for a clinical trial to test its experimental anti-viral drug remdesivir (as used to tackle Ebola virus). With the backing of the **World Health Organisation** the drug is also being trialed in China.

The Maryland based, Nasdaq listed **Novavax** says it is cloning the coronavirus to develop a vaccine, in the same way it developed one for MERS in 2013.

Novavax is looking at several vaccine candidates for animals and hopes to find one for human testing by the end of May.

"Our previous experience working with other coronaviruses, including both MERS and SARS, allowed us to mobilize quickly," said Novavax CEO Stanley Eck.

Fellow Nasdaq minnow **Moderna** has shipped an experimental vaccine to the National Institute of Allergy and Infectious Diseases for testing.

Backed by billionaire hedge fund founder Jim Simons, the Long Island-based private outfit **Codagenix** expects to have a vaccine ready for animal testing in four to six weeks, with one suitable for testing about six weeks later.

The Codagenix know-how is based on recoding the genomes of viruses to render them harmless. The technique is not exactly unknown, as it's been used to eradicate polio and small pox.

And who can forget Australia's very own Relenza anti-influenza **Biota**, which became Alpharetta Georgia's **Nabi**, changed its name to **Aviragen** and then was subsumed as a sub-division of San Francisco's **Vaxart**, popping its head above the parapet to also claim an anti-viral program for Covid-19.

Stem cell therapy to the rescue?

The South China Morning Post reports that a 65-year-old woman on her Covid-19 deathbed walked out of China's Kunming Hospital after being given a stiff shot of mesenchymal stem cells (MSCs).

Two trials are also underway to test the therapy against pneumonia, at a Beijing Military Hospital and Zhongnan Hospital of Wuhan University (yep, in the coronavirus capital).

Could the excitement rub-off on our ASX-listed plays **Mesoblast**, **Cynata Therapeutics**, **Orthocell** and **Regeneus**?

Cynata's Dr Ross Macdonald says the reports look authentic; and he believes that MSCs could be an adjunct in managing patients with serious issues pertaining to Covid-19.

"This is not because MSCs are inherently anti-viral or can act as a vaccine, but more because they have shown benefit in major pathologies associated with infection."

Cynata, we stress, has not mentioned coronavirus in its dispatches and nor has any of the other non-China MSC plays - or not yet anyway. But still, what decent CEO would not give his company a plug?

"The clear advantage of (Cynata's) Cymerus technology (is) the ability to make large quantities of consistent, robust MSCs without having to find gazillions of donors," Dr Macdonald says.

Not everyone's a winner

Your columnist stresses that the coronavirus influence on the sector is not all positive, with some biotechs likely to be affected by supply or other disruptions.

In mid-February, **Cochlear** quickly stepped off the mark by announcing its earnings for the 2019-'20 year were likely to come in at \$270-290 million, compared with the previously guided \$290-300 million.

The reason is that hospitals in China and Hong Kong have delayed cochlear implant procedures to avoid the risk of infection.

The aforementioned Uscom notes that with labs "preoccupied" with the virus, short term revenues are less predictable. In other words, the coronavirus is a distraction as well as an opportunity.

IDT Australia CEO Dr David Sparling told Biotech Daily that his company had no direct supply chain exposure to China at all, and was doubtful that even the company's gowns and protective gear had much to do with the Middle Kingdom.

Dr Boreham's diagnosis:

If you throw enough money and resources at tackling a disease you will get a result, right?

Er, not quite: "cures" for well-researched ailments such as Alzheimer's disease, multiple sclerosis and an array of cancers remain elusive.

But when you've got an ailment that is crippling the global economy, the imperative to find a solution is somewhat more intensive.

Our best guess is that like SARS and MERS, Covid-19 will hang around for years to come, but the ill-effects will be made more tolerable with an effective vaccine and/or improved immunity over time.

In other words, it will become just another disease in the pantheon of maladies blighting humanity.

In the race for a cure, Gilead's remdesivir looks interesting, given it has been used before.

As for the opportunists in the sanitizer game, the surge in demand means tangible revenue gains - and good on them.

But let's be clear: they're hardly breaking new ground technology-wise and their gains will only be short term as other suppliers enter the market.

As for a cure - or lack of one - we suggest that investors hedge their bets with an exposure to the funeral stocks **Invocare** and **Propel Funeral Partners**.

After all, they're the last people to let you down.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. If he doesn't shake hands with you or spare you a square of toilet paper, don't be offended.

NEUREN PHARMACEUTICALS

Neuren says its six-week dose escalation study of NNZ-2591 for Phelan-McDermid syndrome has shown a dose response at four dose levels in mice.

Neuren said that six-week treatment showed greater efficacy than a previous three-week trial and it had identified an optimum dose, which it did not disclose.

Last year, the company said that at three weeks dosing in a mouse model, NNZ-2591 showed “positive effects” for Phelan-McDermid syndrome (BD: Feb 18, 2019).

Today, Neuren said there was no treatment for the syndrome which presented as an intellectual disability, delayed or absent speech, symptoms of autism, low muscle tone, motor delays and epilepsy.

The company said the SHANK3 gene was deleted in mice to mimic Phelan-McDermid syndrome in humans, and it administered either a placebo or four escalating doses of NNZ-2591 to wild type and knockout mice for six weeks and compared the incidence of seizures, as well as measures of anxiety, repetitive behavior, memory, learning, sociability, daily living and motor function.

Neuren said the results were consistent across all measures.

The company said that at the unspecified lowest dose NNZ-2591 was ineffective, at twice the unspecified dose it was partially effective and at four times and eight times the unspecified dose the effect was indistinguishable.

Neuren said the four times dose was the optimum level in the mouse model.

The company said that it would compare the doses with pharmacokinetic data from its planned phase I clinical trial to inform the equivalent human dose for its planned phase II clinical trials.

The company said that the selected optimum dose showed better efficacy at six weeks than at three weeks, indicating that efficacy increased with treatment duration and it planned to test 12-week treatments in phase II clinical trials.

Neuren said that the selected optimum dose was effective at six weeks of treatment in mouse models for Angelman syndrome and Pitt Hopkins syndrome.

Neuren fell 11 cents or 5.4 percent to \$1.94.

KAZIA THERAPEUTICS

Kazia says it has completed recruitment of its 30-patient, phase II, clinical trial of paxalisib, formerly known as GDC-0084, for glioblastoma.

Kazia said it expected to report interim data in April 2020.

Kazia chief executive officer Dr James Garner said that recruitment was completed “well ahead of expectations”.

Kazia was unchanged at 64 cents.

RACE ONCOLOGY

Race says it has commitments to raise \$1.8 million through a placement at 30 cents a share, corner-stoned by Perth’s Merchant Opportunities Fund.

Race said the issue price was a nine percent discount to the last closing price and a 9.5 percent discount to the 20-day volume weighted average price.

The company said that Nascent Capital Partners would be issued 1,500,000 options, exercisable at 45 cents an option and expiring 24 months from the issue date.

Race said the funds would be used to advance its ‘5-path’ clinical development strategy for Bisantrone for acute myeloid leukaemia in 2020.

Race was up 3.5 cents or 10.6 percent to 36.5 cents.

GILEAD SCIENCES AUSTRALIA AND NEW ZEALAND

Gilead says the 2020 Fellowship Research Grants Program has awarded \$300,000 to seven research projects.

Gilead said the projects had a local community focus, which often struggled to secure funding, and focused on HIV, liver disease, invasive fungal infection, haematological malignancies and inflammatory diseases.

The company said the project recipients included the University of Western Australia's Kieran Mulrone for research into fast and accurate diagnostic tests for fungal infections, Melbourne's Alfred Health's Miles Sparrow for development of rapid, point of care testing for therapeutic drug monitoring and faecal biomarker testing in inflammatory bowel disease, the University of New South Wales' Kirby Institute's Nila Dharan for a study to evaluate and compare aging and quality of life among older adults with and without HIV. Gilead said other recipients included the Burnet Institute's Jessica Howell to develop point-of-care testing for liver inflammation and fibrosis in chronic hepatitis B and the Sydney's Royal Prince Alfred Hospital's Jack Heron for a retrospective study to examine past HIV kidney transplants and patient outcomes.

The company said the Peter MacCallum Cancer Centre and University of Melbourne's Shio Yen Tio was awarded a grant to study invasive fungal and bacterial infections in haematological malignancy and stem cell transplant patients, and the Pharmaceutical Research Services' Andrew Pfeffer was awarded funds for a mobile medical centre to treat hepatitis C in high-risk patients.

Gilead said \$US300,000 (\$A454,389) was independently donated to the Kirby Institute's David Cooper Memorial Fund to support local researcher-led studies around the country.

EYEPOINT PHARMACEUTICALS (FORMERLY PSIVIDA)

Eyepoint says revenue for the year to December 31, 2019 was up 345.5 percent to \$US20,365,000 (\$A30,878,431.25) with net loss down 34.1 percent to \$US56,793,000 (\$A86,112,386.25).

Eyepoint said revenue included \$US16,824,000 from sales from its dexamethasone intraocular suspension (Dexycu) and fluocinolone acetonide intravitreal implant (Yutiq). The company said it had cash and cash equivalents of \$US22,214,000 at December 31, 2019 compared to \$US45,261,000 at December 31, 2018.

On the Nasdaq, Eyepoint fell 13 US cents or 9.0 percent to \$US1.13 (\$A1.71).

REDHILL BIOPHARMA

Redhill says revenue for the year to December 31, 2019 was down 24.7 percent to \$US6,291,000 (\$A9,538,729) with net loss after tax up 9.0 percent to \$US42,304,000 (\$A64,143,440).

Redhill said revenue was down due to "the competitive landscape" for its two gastrointestinal specialty products, Donnatal and Enteragam.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picocona (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2019).

Today, the company said it expected to launch Talicia, formerly Heliconda, for Helicobacter pylori in mid-March 2020.

Redhill said it had cash and cash equivalents of \$US29,023,000 at December 31, 2019 compared to \$US29,000,000 at December 31, 2018.

On the Nasdaq, Redhill was up 28 US cents or 6.3 percent to \$US4.73 (\$A7.16).

FEDERAL GOVERNMENT

The Federal Government says North Queensland's Tropical Australian Academic Health Centre is the third Centre for Innovation in Regional Health.

A media release from Federal Health Minister Greg Hunt said the centre was a collaboration between five hospitals and health services, including the Northern Queensland Primary Health Network, James Cook University and the Australian Institute of Tropical Health and Medicine.

The Government said that to be accredited by the National Health and Medical Research Council, the Centre demonstrated research excellence and leadership in research-based clinical care and training.

The media release said the Centre delivered high-quality services to regional and remote communities through health workforce models such as tele-oncology, tackled infectious diseases and non-communicable diseases prevalent in northern Queensland, and established training programs to build the research capability of clinicians.

AZURE HEALTH TECHNOLOGY

Azure says an extraordinary general meeting has passed all resolutions to acquire Invictus Biopharma, with up to 29,522 votes (0.09%) in opposition.

Last month, Azure said it hoped to raise up to \$10 million for a backdoor listing of Invictus' tocotrienols food additive and supplements business (BD: Feb 5, 2020).

Azure was in an extended suspension with a notional last traded price of \$1.146.

CRYOSITE

Cryosite director Andrew Kroger says he has increased his substantial shareholding in the company from 17,815,291 shares (38.02%) to 18,186,450 shares (38.81%).

The Melbourne-based Mr Kroger said that between March 2 and 4, 2020 he acquired 371,159 shares for \$24,872.13 or an average of 6.7 cents a share.

Cryosite was untraded at seven cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has appointed John Sharman as chief executive officer, starting on a base salary of \$480,000 a year, plus superannuation.

Yesterday, Medical Developments said Mr Sharman had resigned as its chief executive officer "to pursue other business interests" but would remain with the company through the transition (BD: Mar 5, 2020).

Today, Universal Biosensors said Mr Sharman would receive 7,094,000 non-voting plan shares in three equal tranches valued at \$780,000 and a limited resource five-year loan to acquire each tranche at 20, 25 and 30 cents each respectively, as a long-term incentive.

The company said Mr Sharman had more than 20 years' experience in corporate finance, banking, private equity and public company leadership, and held a Bachelor of Economics from Monash University and a Master of Applied Finance from Macquarie University.

Universal Biosensors climbed 3.5 cents or 21.9 percent to 19.5 cents with 1.1 million shares traded.

RACE ONCOLOGY

Race says it has appointed Dr John Cullity as non-executive chairman, replacing founding chairman Dr Bill Garner, who will continue as a non-executive director.

In 2018, Race said it had appointed Dr Cullity as a non-executive director, replacing Dr Brendan de Kauwe (BD: Apr 4, 2018).

Today, the company said Dr Cullity was previously a director of health economics (oncology) and strategic pricing at Schering-Plough, head of strategic pricing at Sanofi-Aventis, a principal at the New York-based Torreya Partners and has held leadership roles in oncology business development and licencing.

DIMERIX

Dimerix says it has appointed Prof Hiddo Heerspink Prof Alessia Fornoni, Prof Jonathan Barratt, Prof Lesley Inker and Dr Muh Geot Wong as advisors.

Dimerix said Prof Heerspink would be the chair of the medical advisory board.

The company said that Prof Heerspink was a professor of clinical trials and personalized medicine at the Netherlands-based University Medical Centre Groningen.

The company said the advisory boards would “assist with the analysis and interpretation of data from the two phase II clinical studies expected mid-2020, as well as assist with the design of future studies, including the pivotal phase III study for focal segmental glomerulosclerosis”.

Dimerix fell half a cent or three percent to 16 cents.

ESENSE-LAB

Esense-Lab says it has appointed Itzik Mizrahi as chief executive officer and James Bahen as company secretary, effective from March 9, 2020.

Esense-Lab said Mr Mizrahi would replace interim chief executive officer Piers Lewis and Mr Bahen would replace Sebastian Andre, effective immediately.

The company said the Israel-based Mr Mizrahi would receive a salary of \$NIS540,000 (\$A236,036) and 2,000,000 shares three months from the appointment, 2,000,000 shares upon annual sales of \$2,500,000 and 2,000,000 shares upon annual sales of \$5,000,000. Esense-Lab said Mr Mizrahi had more than 20 years' experience in management and was previously head of clinical at Pfizer Pharmaceuticals Israel and general manager at Actelion Pharmaceuticals.

The company said Mr Bahen had been a company secretary for more than five years and held a Bachelor of Commerce and Graduate Diploma of Applied Finance.

Esense-Lab was up 0.1 cents or 14.3 percent to 0.8 cents with 3.8 million shares traded.