

Biotech Daily

Friday December 16, 2022

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.78 percent on Friday December 16, 2022, with the ASX200 down 56.1 points to 7,148.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 19 fell, three traded unchanged and one was untraded. All three Big Caps fell.

Dimerix was the best, up 1.5 cents or 9.7 percent to 17 cents, with 180,726 shares traded. Next Science and Universal Biosensors climbed more than six percent; Cynata was up 5.1 percent; Impedimed, Micro-X and Resonance improved four percent or more; Immutep and Patrys were up more than three percent; Polynovo rose 2.5 percent; Amplia, Clinuvel, Kazia and Mesoblast were up more than one percent; with Atomo, Nanosonics and Telix up by less than one percent.

Nova Eye led the falls, down 2.5 cents or 9.1 percent to 25 cents, with 1,203 shares traded. Alcidion lost 6.7 percent; Actinogen and Emvision fell more than five percent; Pharmaxis lost 3.3 percent; Antisense, Compumedics, Imugene, Opthea, Orthocell and Starpharma shed two percent or more; Avita, CSL, Genetic Signatures, Medical Developments, Paradigm and Resmed were down one percent or more; with Cochlear, Neuren, Pro Medicus, Proteomics and Volpara down by less than one percent.

THE A TO Z OF DR BOREHAM'S CRUCIBLES IN 2022

By TIM BOREHAM

The long and short of 2022 is that it was a frustrating period for the Australian biotech sector but one with its fair share of rewards as the sector's exponents furthered worthy drugs, diagnostics, devices and doodahs.

While esteemed Biotech Daily editor David Langsam and his team catalogued the daily events across the sprawling sector, the ersatz Dr Boreham cast his eye weekly on a worthy specific company (usually listed, but not necessarily so).

Here's the A-Z of his key findings, pending a Royal Commission, Senate Select Committee inquiry or possibly a censure motion:

A is for Arovella, formerly Suda and an exemplar of the sector's ability to change with the times. Aro-Suda was pursuing spray mist-based drug delivery, but has now abandoned that in favour of Car-T, which is not a T-model Ford but a type of cancer immunotherapy. A is also for Adherium, which is commercialising a device to improve adherence to medications for asthma and chronic obstructive pulmonary disease (COPD). The company's sharpened strategy is based on data generation just as much as the devices, which means medicos can win reimbursement.

B is for bio-bargains, which abounded both here and on the Nasdaq as the market swooned early in the year. Companies in phase III trials are trading at a smidgin of their worth when they were less advanced and often not far above cash backing. We tender Pharmaxis and Dimerix (see below) as evidence.

C is for Covid. But hang on! We're officially over that topic even though the disease remains rampant and swathes of China remain locked down.

So instead, we'll mention Cronos, the medical cannabis market place that has achieved a rare feat for the sector: profitability. The company even paid a dividend -and we're not smokin' anything.

Sadly, the company has also been embroiled in controversy over the circumstances of the departure of chief medical officer Dr Benjamin Jansen.

Which just goes to show that where there's smoke, there's ire ...

D also stands for Dimerix, the kidney diseases specialist in phase III for its lead compound DMX-200, to treat the rare kidney condition focal segmental glomerulosclerosis (FSGS). It's also on the job with the more common diabetic kidney diseases (DKD), the common link being fibrosis, or scarring.

E is for elections - Federal, Victoria and in an important part of the Americas (yep-Brazil). E is also for the California based, ASX-listed EBR Systems, which is developing a cardiac lead to regulate the difficult-to-access left ventricle. The size of a grain of rice, the Wise device doesn't need an in-built battery and is only five to six percent the size of other wireless pacemakers. **F** is for floods, which blighted the east coast at a time when biotech sector valuations were underwater in a more metaphorical sense.

F is also for Firebrick Pharma, which listed in late January on the back of a nasal spray variant of Betadine, to kill the common cold (or 'flu) virus.

Firebrick's chief germ buster Dr Peter Molloy used to lead influenza drug house Biota, so he knows his way around a nasal cavity (so to speak).

G is for G-spot, but because we're a G-rated publication we will settle for the Glorious lung imaging innovator 4D medical, which soon might be able to boast of 'by appointment to the US military' among its early achievements.

The only provider of four-dimensional models of lung function in the world, 4D is focusing on US veterans with serious lung conditions such as constrictive bronchiolitis.

H is for is for Harry and Meghan, but that could be filed under W for 'Who cares?' H is also for heart devices. There's the aforementioned EBR, and Imricor is developing catheters guidable by magnetic resonance imaging, rather than traditional X-ray methods.

I is for inflation, which hasn't exactly applied to biotech share prices. I is also for Inoviq, formerly Bard1 which merged with cancer diagnostics house Sienna Diagnostics. The company is a tad baffling but they must be doing something right given its shares this week rose 20 percent after encouraging results for an ovarian cancer assay.

J is for Jab, or the lack thereof: the private Vaxxas plans to list on the back of a novel device that would deliver vaccines and medications through the skin, rather than via an injection. This one really won't hurt a bit if it gets to commercialization stage.

K is also for 'ker-ching!' as Resapp holders accepted a \$170 million buyout offer from Pfizer. Resapp's mobile telephone software application seeks to identify respiratory disorders based on the nature of the user's cough, but in the end, investors were happy to see Pfizer splutter up the readies.

K is for Kazia, one of the year's biggest disappointments as its co-operative global glioblastoma (brain cancer) trial foundered. Kazia shares have lost more than 90 percent of their value over the last year - more a case of 'kaboom' than 'ker-ching'.

L is for longevity as companies such as Pharmaxis, Starpharma and Immutep keep plugging away. L is also for LBT Innovation, which finally looks to be making progress with its automated Petri dish analysis device.

M is for Morrison, Scott and his multiple ministries. M is also for Marvellous, which describes initial US sales of Telix Pharmaceuticals new isotope system for prostate imaging, called Illuccix.

M is also for magnificent Microba, which listed in April on the back of its tests enabling consumers, clinicians and researchers to measure the gut microbiome.

On November 28, Microba shares bounded more than 50 percent on news that pathology giant Sonic Healthcare would invest just under \$18 million to take a 19.9 percent stake.

N is for nasal swab test and the ever-industrious Rhinomed and perennial Biotech Daily CEO of the Year candidate Michael Johnson. Rhinomed brought a kids-friendly version of its clip-on nose appendage – an alternative to the long 'brain stab' swabs - to market. N is also for 'no money' – and there's a few biotechs who will need to think seriously about where their next dollar is coming from in 2023.

O is for Opthea. Speaking of capital raisings - the ASX and Nasdaq-listed eye diseases house defied the sector's funding drought by raising a minimum \$300 million, via a deal with US life sciences development company Launch Therapeutics. The dosh will support Opthea's phase III trials of its drug candidate for OPT-302, for the hard-to-treat, back-of-the-eye disease wet aged-related macular degeneration (wet AMD).

P is for pivoting: the aforementioned Arovella to Car-T and - arguably - Clinuvel to nonskin related and over-the-counter therapies. Fortunately, we haven't seen anyone eschew drugs in favour of coal mining in Alabama, as one out-of-luck biotech once did. P is also for 'poo test' and Rhythm Bioscience's promising quest to replace the unpopular bowel cancer assay with a blood test.

Q is for Queen, the death of (and long live the King). Q also stands for Qbiotics, the everinteresting unlisted outfit targeting oncologic and veterinary therapies based on biologic material from the Daintree rainforest (a.k.a. nature's pharmacy). Having got a canine cancer treatment to market, Qbiotic's focus has returned to treating two-legged cancers including melanoma and the difficult-to-treat head and neck squamous cell carcinoma

R is for RATs, which have all but supplanted the more accurate but expensive polymerase chain reaction Covid tests. Genetic Signatures was one diagnostic company to surf the PCR boom; now it's emphasizing other indications in its (considerable) testing armoury. Atomo Diagnostics supplied re-badged blood pinprick Covid RATs from a US manufacturer, for professional use only. Given the lack of an approved home-based variant, Atomo shares have lost more than 70 percent of their value this year. Meanwhile, the private, hero-to-zero Ellume called in the administrators; and the FDA rejected an application from Lumos Diagnostics to market its Febridx product in the US. The regulator was concerned the test could not distinguish adequately between bacterial and viral respiratory infections. Rats!

S is for strokes, the nasty affliction striking down 15 million people each year. Emvision and Micro-X are on the case with portable detection units to improve diagnosis, while Clinuvel is launching a trial for a potential treatment.

All we need is a stroke of good fortune for one of these Aussie innovators to become a global hero.

T is for telehealth, an emerging market being pursued by the likes of Adherium, Respiri (asthma detection) and the now de-listed Resapp and the patient management software purveyor Alcidion, which we covered last week.

T also stands for \$280 million market cap Trajan Group, which is becoming a carefullycalibrated force in precision scientific instruments.

U is for the Uncomplicated story of Recce Pharmaceuticals, which is developing a better antibiotic to treat dangerous hospital conditions such as sepsis.

V is for vaccines - not that there are many ASX-listed vaccine plays beyond CSL. By the way, CSL stirred things up early in the piece with its left-field purchase of Swiss kidney diseases house Vifor. Vifor? Vynot, we say.

V also stands for the kiwi breast cancer detection house Volpara Technologies, which is taking a more cost-conscious course under ebullient new American CEO Teri Thomas.

W is for Woke, the overused pejorative descriptor for those with progressive views. It also stands for Woke Pharmaceuticals, the unlisted psychedelic play with far-out clinical programs for magic mushrooms and LSD.

X is for Xanadu, one of Actinogen's clinical programs for Alzheimer's disease. The company is batting on nicely after earlier setbacks, but sadly Olivia Newton John - star of 1980s musical Xanadu - is not. Vale, Olivia, whose legacy will be remembered with the Olivia Newton-John Cancer Research Institute (and wellness centre).

Y is a crooked letter that can't be straightened, a response that every exasperated parent of a toddler asking "why" has resorted to.

Y is also for 'yes,' the response sought by multiple Aussie biotechs seeking FDA approval. It's a hard slog and the answer is often filed under 'N'.

Z is for zzzz and the enduring performance of Resmed in the sleep apnoea sector. Just for a change, this month we also covered Resmed wannabe Fisher & Paykel Health, a sleepy (sorry) Kiwi player albeit with a tidy \$10-billion plus worth.

Zzzz is also the sound of your columnist on the sofa at 4pm on Christmas Day, happily engorged with Heart Foundation-approved plum pud and the finest red that Dan Murphy's bargain bin can offer.

See you next year!

BIOTECH DAILY SUMMER PUBLISHING DATES

Biotech Daily will close for the Summer break next Thursday December 22, 2022 and reopen on Monday January 23, 2023. This was the last Dr Boreham Crucible for the year, with the column returning on Friday, February 3, 2023.

SYNCHRON INC

Synchron says it has raised \$110 million to accelerate development of its Synchron Switch platform product, a brain-implanted computer interface.

The Melbourne and New York-based Synchron said that the Switch was a brain computer interface, implanted in the blood vessel on the surface of the motor cortex of the brain via the jugular vein, through a minimally-invasive endovascular procedure.

The company said that the Switch was "designed to detect and wirelessly transmit motor intent ... [from] the brain, restoring a capability for severely paralyzed patients to control personal devices with hands-free point-and-click".

According to an infographic provided by Synchron, the Switch platform sends neural signals to a transmitter implanted in the chest, which sends Bluetooth signals to a computer outside the body, and then uses machine-learning to translate the signals into specific commands.

The company said that the Switch platform received US Food and Drug Administration Breakthrough Device Designation in 2020 and currently was in human clinical trials in the US and Australia.

Synchron said the raise was led by the Chicago, Illinois-based Arch Venture Partners, and included investments from Gates Frontier, the investment venture arm of Microsoft and Bill Gates, as well as Jeff Bezos' Bezos Expeditions Fund, Reliance Digital Health,

Greenoaks, Alumni Ventures, Moore Strategic Ventures, Project X, and Khosla Ventures. Synchron said that the most recent capital raise brought the total amount raised since it was founded in 2016, to \$212 million.

Arch managing-director Robert Nelsen said "our approach has always been to pair great science and technology with remarkable teams to build disruptive companies".

"The technology we witnessed at Synchron is helping people with previously untreatable conditions regain connection to the world," Mr Nelsen said.

Synchron co-founder and chief executive officer Dr Tom Oxley said the company had "an opportunity to deliver a first-in-class commercial [brain computer interface]".

"The problem of paralysis is much larger than people realize ... 100 million people worldwide have upper limb impairment," Dr Oxley said.

"We are extremely excited to work with Arch and this world-class syndicate to bring this technology to the people who need it," Dr Oxley said.

Synchron is a private company.

POLYNOVO

Polynovo says its \$17 million share plan at \$1.90 a share had \$35.27 million in applications and it increased the plan to \$20 million, taking the total raised to \$53 million. In November, Polynovo said it had raised \$30 million in a placement at \$1.90 a share, and hoped to further raise \$3 million in a directors' placement and \$17 million in a non-underwritten retail share plan (BD: Nov 22, 23, 2022).

Today, the company said that given the response it increased the plan by \$3 million, to a maximum of \$20 million.

Polynovo said that the directors' placement had raised \$3 million, subject to shareholder approval.

Polynovo chairman David Williams said it was "humbling and unique to see the way in which shareholders support the company financially and morally for the impact [Novosorb biodegradable temporizing matrix] has on people's lives."

Polynovo was up five cents or 2.5 percent to \$2.05 with 2.25 million shares traded.

NOXOPHARM

Noxopharm says a \$1,496,654 Hudson Institute of Medical Research grant will support subsidiary Pharmorage develop its Sofra technology for inflammation and autoimmunity. Noxopharm said that the National Health and Medical Research Council awarded Melbourne's Hudson Institute the four-year grant to support "innovative research into novel treatments for autoimmune diseases".

The company said that the Hudson Institute's Prof Michael Gantier, along with the Australian National University's Dr Julia Ellyard and Prof Ben Corry were developing a new class of RNA therapeutics that selectively inhibited the TLR7 protein, which was over-activated in diseases like lupus.

Noxopharm said that Sofra was a technology platform for inflammation and autoimmunity which would "provide the basis for active development of a growing pipeline of new proprietary drugs".

Noxopharm chief executive officer Dr Gisela Mautner said the research was "key to our proprietary Sofra technology platform, which is a fundamental component of the preclinical pipeline we are building as part of our multi-platform strategy".

Noxopharm was up 0.5 cents or 3.45 percent to 15 cents with 2.25 million shares traded.

RESPIRI

Respiri says that Hand Family Healthcare will use its Wheezo remote patient monitoring program for asthma and chronic obstructive pulmonary disease.

Respiri said that its partner Access Telehealth would provide a full remote patient monitoring program (RPM) to the Clovis, New Mexico-based Hand Family Healthcare, that included the Remotli platform, patient engagement and remote monitoring, and that the remote patient monitoring current procedural terminology reimbursement claims would generate revenue within two months of patients beginning the program.

The company said that it had healthcare customers in six US states, up from five last week (BD: Dec 7, 2022).

Respiri was up 0.4 cents or 9.8 percent to 4.5 cents with 1.2 million shares traded.

NANOSONICS

Fidelity Management and Research (FMR) says it has reduced its holding in Nanosonics from 20,611,647 shares (6.82%) to 16,963,930 shares (5.62%).

The Wilmington, Delaware-based Fidelity said that between November 10 and December 13, 2022 it sold 3,647,717 shares for prices ranging from \$4.35 to \$4.89 a share.

Nanosonics was up three cents or 0.7 percent to \$4.38 with 6.2 million shares traded.

MEDADVISOR

Regal Funds Management Pty says it has increased and been diluted in Medadvisor from 30,605,090 shares (6.99%) to 31,969,200 shares (5.88%).

The Sydney-based Regal said that between August 1, and December 13, 2022 it bought and sold shares, with the single largest purchase on August 1 of 7,330,414 shares for \$1,026,258 or 14 cents a share.

In August, Medadvisor said its institutional and retail rights offer at 14 cents a share raised \$14.6 million (BD: Aug 18, 2022).

Medadvisor was unchanged at 22 cents.

PARADIGM BIOPHARMACEUTICALS

Allianz SE says it has increased its holding in Paradigm from 16,378,604 shares (6.08%) to 20,215,330 shares (7.09%).

The Munich, Germany-based Allianz said that it bought and sold shares between August 25 and December 13, 2022 at prices ranging from \$1.1792 to \$1.6275 a share. Paradigm fell 1.5 cents or 1.15 percent to \$1.295 with 1.4 million shares traded.

BIONOMICS

Bionomics says it has appointed Dr Spyridon Papapetropoulos as a director and the company's chief executive officer on \$US555,000 (\$A826,476) a year.

Bionomics said that interim executive chair Dr Errol De Souza would continue as the nonexecutive chair.

The company said that Dr Papapetropoulos would begin his role on January 5, 2023. Bionomics said that Dr Papapetropoulos was an "experienced" biopharmaceutical executive and neuroscientist with a 25-year career focused on central nervous system disorders.

The company said that previously Dr Papapetropoulos was Vigil Neuroscience chief medical officer, Acadia Pharmaceuticals chief development officer, Swanbio Therapeutics chief executive officer and Cavion chief medical officer.

Bionomics said that Dr Papapetropoulos had also worked at Biogen, Allergan, Pfizer, and Teva Pharmaceuticals and had filed multiple investigational new drug applications and overseen drug development programs.

Bionomics said that Dr Papapetropoulos held a Doctor of Medicine and Doctor of Philosophy from the University of Patras in Greece, and worked at the Department of Neurology of the University of Miami, School of Medicine in Florida.

The company said that Dr Papapetropoulos would be paid a base salary of \$US525,000 (\$A780,252), including health benefits of \$US30,000 a year, a short-term incentive of upto 50 percent of his base salary, and long-term incentives of 27,067,015 options,

exercisable at the five-day volume-weighted average price prior to the grant date, vesting over three years, subject to shareholder approval.

Bionomics said that Dr De Souza would be entitled to compensation arrangements in line with those under his existing employment contract until June 30, 2023, as well as 100 percent of his target bonus for 2022-'23, and subject to shareholder approval, he would be issued a further 10,000,000 options to acquire shares at 5.2 cents a share. Bionomics was up 0.5 cents or 9.6 percent to 5.7 cents.