



Biotech Daily

Friday September 20, 2019

Daily news on ASX-listed biotechnology companies

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- * **DR BOREHAM'S CRUCIBLE: PHARMAUST**
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- * **JAPAN PATENT FOR RECCE ANTIBIOTICS**
- * **RESPIRI INDIA PRE-MARKET LAUNCH OF WHEEZO FOR ASTHMA**
- * **CVC BELOW 5% IN PROBIOTEC**
- * **GI DYNAMICS CEO \$663k BASE SALARY, 58m OPTIONS, 55m SHARES**

MARKET REPORT

The Australian stock market was up 0.2 percent on Friday September 20, with the ASX200 up 13.3 points to 6,730.8 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and one was untraded. All three Big Caps fell.

Yesterday's 18.2 percent worst, Antisense, was today's best, up one cent or 15.9 percent to 7.3 cents, with 5.9 million shares traded.

Paradigm climbed 9.05 percent; Universal Biosensors was up 5.3 percent; Genetic Signatures and Resonance improved four percent or more; Medical Developments was up 3.2 percent; Impedimed, Optiscan and Osprey rose more than two percent; Clinuvel, Cynata, Nanosonics, Pro Medicus, Proteomics, Starpharma and Telix were up one percent or more; with Mesoblast and Opthea up by less than one percent.

Alterity (Prana) led the falls, down 0.3 cents or 9.1 percent to three cents, with 600,000 shares traded.

Neuren lost 7.7 percent; Oncosil was down 5.6 percent; Pharmaxis fell 4.55 percent; Compumedics, Dimerix and Orthocell were down more than three percent; Cyclopharm and Volpara shed more than two percent; Avita, Next Science and Polynovo were down more than one percent; with Cochlear, CSL and Resmed down by less than one percent.

[DR BOREHAM'S CRUCIBLE: PHARMAUST](#)

By TIM BOREHAM

ASX code: PAA

Share price: 14.5 cents; **Shares on issue:** 280,971,192; **Market cap:** \$40.7 million

Executive chairman: Dr Roger Aston

Board: Dr Roger Aston, Rob Bishop, Neville Bassett, Sam Wright

Financials: (Year to June 30, 2019): sales revenue \$3.7 million (up 28%), other revenue \$694,000 (up 63%), loss of \$1.6 million (previously \$2.5 million deficit), cash of \$2.1 million (up 11%), borrowings of \$324,614 (down 23%).

Identifiable major holders: Hybrid Holdings (Darcy family superannuation trust) 7.53%, Dr Roger Aston 5.35%, Gerard and Gillian Van Blommestein 4.36%, Longbow Croft Capital (Rob Bishop) 2.92%, Peter Howells 1.55%, Douglas Brewster Kitchen 1.48%

The notion of 'everything old is new again' applies not just to fickle fashion trends, but to drug development as well.

Drug reformulations are all the rage and it's not such a bad thing. Think of Paradigm Biopharmaceuticals with its promising efforts to repurpose a 60-year old drug - previously used to treat deep vein thrombosis and bladder diseases - as an orthopaedic treatment. Or Suda, with a range of oro-mucosal (spray) formulations. Or Medical Developments with Pentrox, a tizzed up version of a front-line pain treatment used here since 1975.

Pharmaust is reviving an old animal drug - a parasitic sheep drench called monepantel - as a cancer curative for both animals and humans. Marketed by Eli Lilly's animal health arm Elanco as Zolvix, the treatment has been long approved in Europe, the UK and here.

Monepantel is thought to inhibit the mTOR pathway which refers to mechanistic target of rapamycin: not a Harry Potter or Tolkien reference but a well-known oncology target.

"The fact that monepantel is already approved for animals in a number of major jurisdictions means that the development process is cheaper than it would be if monepantel were a new [approved pharmaceutical ingredient]," the company says.

Through its Epichem subsidiary, Pharmaust provides export award-winning synthetic and medical chemistry services (contract research work) at its accredited Perth facilities.

Travelling through time

Pharmaust has a long, convoluted ASX history, having listed in October 2001 as Echo Technologies. Echo's pursuits at the time were travel related, including an outfit called Tardis Travel.

By 2005, Pharmaust had turned from sonic screwdrivers to mimotopes (research grade peptides for the drug discovery) and by 2010 Epichem was well-established as a contract research facility.

Epichem provides products and services in synthetic and medicinal chemistry to the drug discovery and pharmaceutical industries. Specialties include custom synthesis of analogue libraries, scaffolds and intermediates; and reference standards of drug impurities, degradants and metabolites.

Out in the paddocks, meanwhile, a clinical oncologist and part-time sheep farmer named Prof David Morris fiddled with monepantel and chanced on its anti-cancer properties.

A spin off from St George's Hospital in Sydney, where Prof Morris works, Pitney Pharmaceuticals negotiated an option for the animal cancer rights with Novartis (now Elanco) in 2012. In return for handing over the rights, Elanco gets first dibs on any animal oncology drug developed by Pitney (now, of course, Pharmaust).

Pitney Pharmaceuticals was acquired by Pharmaust in 2015 in a \$6 million scrip deal that amounted to a back-door listing of Pitney.

Pitney was run by Dr Roger Aston, now Pharmaust's executive chairman. Dr Aston needs no introduction in biotech circles as the former chair of Mayne Pharma and current chair of Resapp Health and director of Oncosil Medical, not to mention founder of Psivida (now the US-based Eyepoint) and owner of a Scottish castle.

Along the way, Pharmaust has also shored up patent rights with St George's Hospital's commercialization subsidiary New South Innovations. In 2017 Pharmaust also acquired the patents to 50 anti-cancer compounds from Japanese crop protection group Nihon Nohyaku. This intellectual property is "related to but distinct from" monepantel.

Pharmaust is negotiating with Elanco to develop the veterinary health applications of monepantel, but given Elanco's monepantel composition patent starts expiring in 2023 the company may have free rein after that date anyway.

Elanco hived-off from pharma giant Eli Lilly last year and listed in the US, raising \$US1.5 billion. A key benefit of the Elanco tie-up is that Pharmaust can access the former's safety, toxicology and chemistry data used to support the sheep drench approvals.

"I personally had a bit of concern giving a cancer product to sheep that ends up on someone's dinner table," Dr Aston says.

"We downloaded the Novartis dossier and found that because (monepantel) is part of the food chain, they had done extensive safety studies."

While other canine cancer drugs are on the market, Pharmaust claims they are limited because of the side effects that the all-natural monepantel does not produce.

Adverse tox events in cancer chemotherapy are one of the key limiting factors in effective treatment.

What's happened and what's next

A previous pilot phase II canine study in 2017 and then a further study last year showed the drug was effective at improving progression-free survival (the length of time the pooch lives with the disease without it getting worse).

Of the four dogs treated in the 2017 study, three recorded tumor regression of between 2.0 percent and 19 percent, with an average shrinkage of 11 percent. A later trial in 2018 enrolled seven hounds with lymphoma and showed that monepantel significantly induced progression-free survival in six of them.

One historical problem with monepantel has been its foul taste - like floor polish we gather - which was fine for delivering down the throat of sheep via drench tubes but not for discerning dogs. Happily, the company has been able to re-formulate the medicine in a "taste neutral" tablet formulation that the dogs will take from the hand of the owner.

In alliance with Elanco, Pharmaust is preparing for a pivotal phase II clinical trial for dogs with B-cell lymphoma.

The New South Wales Department of Primary Industries gave the ethical go-ahead for the trial in July, expected to start recruiting shortly (in case you're wondering the dogs aren't required to sign the consent forms).

Led by the University of Melbourne's U-Vet Werribee Animal Hospital, the trial expects to treat 15 to 20 dogs initially, but the cohort will be expanded if the positive results continue.

On the human side, a phase I study at the Royal Adelaide Hospital established a reduction in cancer markers. Of the eight patients who started, two discontinued because of the drug palatability (foul taste) and two pulled out for other reasons.

Now the company is looking for clinical sites interested in doing a trial in hard-to-treat cancers such as glioblastoma or pancreatic cancer.

"We are talking to clinicians in Europe, UK and Australia to find which cancer we are going to target," Dr Aston says. "Once we have found which cancer we want to go for, we will do a major phase II study as we did for dogs."

Unlike mice, the standard lab guinea pigs, dogs are closely related to human physiology and most canine cancer drugs are reformulations of human cancer therapies.

Finances and performance

After years of important but unexciting development, Pharmaust has appeared on the radar of excitable investors with the stock soaring 255 percent since late June.

While it's hard to pin down an exact catalyst, Dr Aston says the market expects a "meaningful corporate event" if the trial succeeds. This could involve Elanco buying the drug - or, the cheaper option - Elanco buying Pharmaust outright.

Dr Aston notes that Elanco is not averse to some acquisitive va-va voom, having just agreed to buy Bayer's animal health unit for \$US7.6 billion of cash and scrip.

Elanco's also recently purchased the vet oncology company Aratana.

In the meantime, Pharmaust benefits from the steady-state Epichem business, which generated \$3.7 million of revenue in the 2017-'18 year and is poised to turn over \$4.2 million this year.

As of June 30, Pharmaust had cash of \$2.09 million, bolstered by a \$2 million two-for-one rights issue in February. Initially, the effort raised only \$1.3 million, but the shortfall offer gathered a further \$700,000.

With the offer struck at 2.5 cents, the true believers were bang on the money and now have a howling 440 percent gain.

Pharmaust has raised \$13.75 million since the 2013 reverse listing. The company also pocketed \$627,250 from a research and development incentive refund, applicable for the 2017-'18 year.

Pharmaust also has \$325,000 of borrowing through a facility with the export credit agency Export Finance Australia. This relates to a \$466,000 loan for Elanco to build a second lab facility in Perth.

A \$750,000 for an upgrade of its original lab in 2015 has been repaid.

Dr Boreham's diagnosis:

On the pet side, Pharmaust is riding the theme of ageing Western populations and the rise in single-person households, which elevates Molly and Ripley to two-legged status.

One in four dogs die of cancer, including half of dogs over 10 years old. As Dr Aston notes, even extending a beloved pet's life by six quality months makes for an attractive commercial market.

Americans spend \$US70 billion on pet care annually, including \$US17 billion on vets and \$US10.2 billion on drugs.

Naturally, the potential of a non-toxic cancer drug for the human market is compelling, but the company still has a long way to go.

In the meantime, Epichem ticks over decent revenue and keeps the lights burning at its Perth HQ.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. While a polished individual, he can't recall imbibing floor cleaner – not knowingly, at least.

GI DYNAMICS

GI Dynamics says data from 871 patients on its Endobarrier for type 2 diabetes and obesity register shows reductions in blood glucose levels, weight and blood pressure. GI Dynamics said the worldwide Endobarrier registry evaluated the risks and benefits of Endobarrier.

The company said data, was presented by the University of Freiburg's Dr Katherina Laubner in a poster titled 'Duodenal-jejunal Bypass Liner (DJBL) for Treatment of Type 2 Diabetes and Obesity – The Risk: Benefit Ratio from the Worldwide EndoBarrier Registry in 871 Patients' at the European Association for the Study of Diabetes meeting in Barcelona on September 19, 2019..

GI Dynamics said the registry data showed reductions in HbA1c or blood glucose levels, weight, systolic blood pressure and cholesterol at the time of Endobarrier explant.

The company said that patients with a higher HbA1c at baseline showed greater reductions at Endobarrier explant.

Dr Laubner said the data "highlights clinically significant reductions in HbA1c, 1.2 percent absolute mean reduction, and weight, 13.7kg mean reduction, as well as improvements in associated cardiovascular metrics".

Dr Laubner said there was an average reduction in systolic blood pressure of 7.4mmHg and a 0.55 mmol/L cholesterol reduction.

GI Dynamics was untraded at 3.3 cents.

RECCE PHARMACEUTICALS

Recce says the Japan Patent Office has granted it a patent for its antibiotics including Recce-327 for Gram-positive and Gram-negative bacteria and superbugs.

Recce said the patent, titled 'Copolymer for use in a method of treatment of a parenteral infection' would protect its intellectual property until November 2035.

The company said the patent contained 13 claims and related to methods of manufacture, administration and application to treat a broad range of common human infections.

Recce was up five cents or 17.9 percent to 33 cents, with 1.96 million shares traded.

RESPIRI

Respiri says it will conduct a pre-market launch of its Wheezo asthma monitor in India through three healthcare institutions, beginning in the first week of October 2019.

Respiri said the pre-market use of Wheezo would be at North and South Indian healthcare institutions with more than 4,500 beds.

The company said 50 Wheezos would facilitate clinical acceptance and treatment protocols in the lead up to a complete roll out of Wheezo to patients.

Respiri chief executive officer Mario Gattino said, "the clinical entry into the Indian market is a significant milestone for the company".

Respiri was up 0.8 cents or 10.4 percent to 8.5 cents.

PROBIOTEC

CVC Limited says it has ceased to be a substantial shareholder in Probiotec, selling 5,576,806 shares for \$9,736,476 or \$1.75 a share.

Last year, Probiotec director Alexander Beard, the Sydney-based CVC and Stinoc said they held 5,502,806 shares or 9.05 percent of the company (BD: Mar 27, 2018).

Probiotec fell one cent or 0.6 percent to \$1.79.

GI DYNAMICS

GI Dynamics says chief executive officer Scott Schorer base salary is \$US450,000 (\$A663,030) with an annual incentive bonus of up to 50 percent of his annual salary.

GI Dynamics said Mr Schorer would receive options over 1,169,545 US shares exercisable at \$US1.12 a share, equivalent to 58,477,250 Chess depository interests (CDIs) exercisable at 3.3 cents each within 10 years, vesting over four years.

The company said that Mr Schorer would also receive 1,106,058 performance shares equivalent to 55,302,900 CDIs, pending enrolment in stage 1 of the current Endobarrier clinical trial, US Food and Drug Administration safety approval to continue enrolment and on attainment of \$US5 million from revenue, distributions from an Apollo Sugar joint venture or transfer fee income from an Apollo Sugar joint venture.