# Biotech Daily

Friday July 31, 2020

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: RESONANCE UP 7%; OSPREY DOWN 9%**

*** DR BOREHAM'S CRUCIBLE: DIMERIX**

*** CLINUVEL RECEIPTS DOWN 9% TO $29m**

*** PHARMAXIS RECEIPTS UP 13% TO $7.8m**

*** G MEDICAL H1 RECEIPTS DOWN 13% TO $2.2m**

*** NUHEARA RECEIPTS UP 44% TO $3.4m**

*** BIOXYNE RECEIPTS UP 61% TO $2.8m**

*** MGC RECEIPTS UP 27% TO $2.1m**

*** OPTISCAN RECEIPTS $1.3m**

*** CORRECTION: DORSAVI**

*** RHYTHM RIGHTS FOR $3.6m TO TAKE TOTAL TO $6m**

*** BTC SELLS BIO101 FOR $500k**

*** AZURE COMPLETES PHASE II NASH, NAFLD PROTOCOL**

*** SCOTT KIRKLAND INCREASES, DILUTED TO 5% IN EMVISION**

*** RYAN LAWS, SKAHA INVESTMENTS BELOW 5% IN EMVISION**

*** SIMAVITA: TIGA 17%, FIFTY-SECOND 16%, DUSSMAN 10%, CHEVRON 9%**

*** MCRAE DILUTED TO 31% IN NEUROSCIENTIFIC**

*** VOLPARA 852k CEO, DIRECTOR OPTIONS AGM**

*** ANTERIS PLEADS SCHULTZ TO 31% FALL, BUT NO ASX QUERY**

## MARKET REPORT

The Australian stock market fell 2.04 percent on Friday July 31, 2020, with the ASX200 down 123.3 points to 5,927.8 points. Eleven of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and one was untraded. All three Big Caps fell.

Resonance was best, up one cent or 6.9 percent to 15.5 cents, with 148,557 shares traded. Imugene climbed 5.4 percent; Optiscan, Telix and Uscom rose more than two percent; Compumedics, Impedimed, Proteomics and Volpara improved more than one percent; with Kazia and Neuren up by less than one percent.

Osprey led the falls, down 0.4 cents or 9.1 percent to four cents, with 64.8 million shares traded. Next Science lost 6.9 percent; Dimerix, Genetic Signatures, Immutep and Nanosonics were down more than five percent; Oncosil, Paradigm, Polynovo and Starpharma fell four percent or more; Amplia and Antisense were down more than three percent; Medical Developments and Orthocell shed more than two percent; with Avita, Clinuvel, Cochlear, CSL, Mesoblast and Nova down more than one percent.

# DR BOREHAM'S CRUCIBLE: DIMERIX

**By TIM BOREHAM**

**ASX code:** DXB

**Share price:** 44.5 cents

**Shares on issue:** 197,749,297

**Market cap:** $88.0 million

**Chief executive officer:** Dr Nina Webster

**Board:** Dr James Williams (chairman), Dr Webster, Hugh Alsop, Dr Sonia Poli

**Financials (three months to June 30, 2020):** revenue nil, cash burn $1.25 million, cash balance $7.8 million, quarters of available funding 6.2

**Identifiable major holders:** Peter Meurs 13%, Bavaria Bay Pty Ltd 4%, Yodambao Pty Ltd 3%.

Collective memo to biotech chiefs: bring out your good news now because investors are all-ears.

Having almost doubled after being linked to a global Covid-19 trial program in June, Dimerix shares this week vaulted as much as 42 percent after the company released top-line results from one of its two trials related to kidney disease.

The programs share the common trait of tackling fibrosis, or scarring, of the kidneys or lungs.

In laychap's terms, the phase IIa study showed Dimerix's lead molecule DMX-200 to be safe in terms of treating the rare disease focal segmental glomerulosclerosis (FSGS).

Being safe is always nice, but the study also showed a reduction in a key biomarker called proteinuria, which is excess protein in one's pee (also known as frothy urine).

Dimerix investors are now waiting eagerly for the pending results of a large trial pertaining to diabetic kidney disease, which like FSGS, has been granted orphan indication by US and European regulators.

"This is clearly very exciting news for our company," says chief executive Dr Nina Webster.

The Covid-19 stuff - which relates to acute respiratory distress syndrome (Ards) - adds further intrigue to the Dimerix story.

## Dimerix through the ages

Dimerix was founded in 2004 by Dr James Williams and former Macquarie Group adviser Liddy McCall, based on technology developed at the University of Western Australia. The Williams-McCall team co-founded Tessitura and then biotech investor Yuuwa Capital.

Dimerix Bioscience was acquired in July 2015 by the ASX-listed Sun Biomedical, which has dabbled in ventures ranging from illicit drug testing, heart valve devices and asthma diagnostics.

Sun Biomedical changed its name to Dimerix Limited in November 2015. Patent lawyer and scientist Kathy Harrison was appointed inaugural CEO in August 2017, having been the company's sole employee when she joined in 2014.

In August 2018, the company appointed Dr Webster as CEO, with Ms Harrison moving to the chief operating officer role (she left the building in November that year).

Dr Webster had held senior positions at drug companies including Wyeth Pharmaceuticals (now Pfizer), Acrux and Immuron.

## Meeting unmet needs

DMX-200, also known as propagermanium (and we've never met an improper germanium) works - or is thought to work-– by reducing cell inflammation. It does this by blocking the signalling process by which inflammatory cells move to the kidney, thus preventing fibrosis or scarring.

Known as a chemokine receptor (CCR2) antagonist, DMX-200 is being tested as an adjunct therapy to patients taking the current standard of care, the blood pressure drug irbesartan (as a so-called angiotensin receptor blocker).

FSGS attacks the kidney's filtering units - glomeruli - causing irreversible scarring and permanent kidney damage (and often failure).

The condition is rare, affecting about 210,000 people (including kids as young as two years). In the US about 80,000 are afflicted, with around 5,400 new cases a year.

Furthermore, 40 percent of those lucky enough to get a kidney transplant have a recurrence of the disease for unknown reasons.

"There's been no real innovation in the kidney space for 18 years," Dr Webster says. "That's because trials have been extremely long, as the endpoint has been end stage renal failure which could take years."

Crucially, the US Food and Drug Administration has accepted a surrogate endpoint of proteinuria, as a measure of the rate of kidney disease progression.

"That means the trials can be months instead of years," Dr Webster says.

**Leaping into Action in the clinic**

The phase IIa trial, dubbed Action, showed that DMX-200 was safe and well tolerated - and also reduced proteinuria levels.

The trial enrolled 10 patients across Australian sites. Ultimately seven patients met the criteria, with three omitted for various reasons (one of them went on holiday and forgot to take their meds).

A crossover protocol meant each patient was treated with DMX-200 and also with the placebo for a 16-week period, with a six-week cleansing break in between.

“[The study] was not powered for statistical significance but it was designed to derive maximum insight from a small number of patients,’’ says nephrologist and trial investigator Dr Muh Geot Wong of Sydney’s Royal North Shore Hospital.

The phase IIa study met the primary and secondary endpoints of being safe and well tolerated.

The double-blind, randomized, placebo-controlled, cross-over design trial showed an average 29 percent reduction in proteinuria, compared to placebo.

Six of seven patients (86 percent) had reduced proteinuria relative to placebo, with two of them (29 percent) achieving a 40 percent or more reduction.

The patients had had a stable dose of the standard of care, irbesartan, with the trial protocol compensating for any proteinuria reduction resulting from this standard-of-care treatment.

While the study was short and petite, Dr Webster says it was designed to derive maximum insight from a small number of patients while retaining the ability for a flexible number of patients to complete the study.

“As such, the study delivered encouraging data which supports further development of DMX-200 in FSGS,” she says.

Under the local Therapeutic Goods Administration’s special access scheme, patients from both studies will continue to receive treatment.

Meanwhile, the phase II diabetic kidney disease trial has enrolled 46 patients, with 40 required to finish in order to statistically adequate.

While it shares orphan status with FSGS, diabetic kidney disease is much more prevalent in the western world.

“About 40 percent of diabetes sufferers have kidney disease and they might not even know it,” Dr Webster says.

Because the trial sites have been in Australia, the company has largely avoided Covid-19 related delays.

**A recap on REMAP-CAP**

Dimerix's share price-shifting Covid-19 news related to DMX-200 being selected for use in a mega global study on acute respiratory distress syndrome (Ards).

The study is called Randomized Embedded Multifactorial Adaptive Platform, known to friends as "Remap-Cap".

An inflammatory condition afflicting the lungs, Ards is the usual cause of coronavirus casualties.

Counter-intuitively, the inflammation is caused by the immune system over-reacting to the presence of the virus.

Ards, of course, is being targeted by the likes of Mesoblast and Cynata Therapeutics using different science.

With a target of recruiting 7,000 patients across 200 sites in 15 countries, Remap-Cap aims to prove up multiple drugs and nominate them for fast track regulatory approval and development.

Remap-Cap is funded by a number of governments and is endorsed by the World Health Organisation.

Dr Webster says the Remap-Cap study uses "adaptive" design, which in effect means it is flexible in following the pandemic around geographies and regions.

The study, of course, will tilt funding to the most promising drug or drugs.

She says it's a moot point as to how long any drug would take to develop, but the short answer is much quicker than normal.

"Most territories are receptive to emerging use approval. As soon as there's an efficacy signal there is a fast pathway to clinical practice.

**Here's back-up …**

We should not forget Dimerix's secondary candidate DMX-700, which is pitched at chronic diseases such as chronic obstructive pulmonary disorder (COPD).

Dr Webster says while DMX-700 has a very different mechanism of action to DMX-200, "both are commercially attractive".

Synonymous with smoking, COPD has created a market for treatments valued at around $US14 billion ($A20 billion) a year.

**Finances and performance**

Following the Ards announcement, Dimerix in June wasted no time raising $5.8 million in a placement, at 36 cents a share (an 18 percent discount).

As of the end of the June quarter the company had $7.8 million in the bank - enough to cover the phase II trials.

“We will always continue to assess our capital needs to support our longer-term strategies,” Dr Webster says.

These plans include a potential phase III kidney program, the preclinical work on DMX-700 and, of course, anything that evolves from the Ards program.

Over the last 12 months Dimerix shares have traded between 8.7 cents (September 10, 2019) and 47 cents (July 30, 2020).

**Dr Boreham’s diagnosis:**

Should DMX-200 be developed as an Ards therapy, the upside is obvious.

The Remap-Cap tie-up involves Dimerix providing the drug for free, in return for the program funding the trial. Given Dimerix has rights to the data, there’s not much to lose in that the results will add insights into the kidney and other programs.

Dr Webster notes the average pandemic lasts 12 to 36 months, which implies that Dimerix might miss out this time around … or perhaps not.

In any event Ards is also prevalent in conditions such as pneumonia, so attractive markets continue to beckon.

“With Ards overall, 30 to 40 percent of patients will not come out of hospital,” Dr Webster says. “It’s a high mortality rate.”

Dr Webster dubs Dimerix a “compelling proposition”, given its programs are in multiple markets with high unmet needs.

Investor focus now turns to the results from the diabetic kidney disease trial, with the last patient dosed in July.

With top-line results due in four to six weeks, investors don’t have to toss and turn for too long.

***Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. The last time he looked he was the proud owner of two kidneys with no frothy urine.***

## CLINUVEL PHARMACEUTICALS

Clinuvel says its receipts from customers for the year to June 30, 2020 were down 9.1 percent to $29,288,000 compared to the previous corresponding period.
Clinuvel said the revenue primarily came from sales of its Scenesse erythropoietic protoporphyria, which decreased due to the economic impact of the Covid-19 pandemic.
The company said receipts for the three months to June 30, 2020 were down 20.0 percent to $10,403,000, and it had cash and equivalents of $66,747,000 at June 30, 2020, compared to $54,269,000 in cash at June 30, 2019.
Clinuvel fell 36 cents or 1.6 percent to $22.04 with 138,102 shares traded.

## PHARMAXIS

Pharmaxis says its receipts from customers for the 12 months to June 30, 2020 were up 12.8 percent to $7,775,000 compared to the previous corresponding period.
Pharmaxis said the customer receipts came from sales of its Bronchitol for cystic fibrosis and its asthma diagnostic Aridol.
The company said it had cash and cash equivalents of $14,764,000 at June 30, 2020 compared to $31,124,000 at June 30, 2019.
Pharmaxis was unchanged at 8.3 cents.

## G MEDICAL INNOVATIONS

G Medical says its customer receipts for the six months to June 30, 2020 were down 12.7 percent to $US2,217,000 ($A3,081,290).
G Medical said the customer receipts came from sales of its vital sign monitoring products including its Prizma smartphone case and its G Medical Patch remote monitor.
The company said it had cash and cash equivalents of $US543,000 at June 30, 2020 compared to $US352,000 at June 30, 2019.
G Medical fell 0.5 cents or 7.5 percent to 6.2 cents with 2.5 million shares traded.

## NUHEARA

Nuheara says it receipts from customers for the year to June 30, 2020 were up 43.7 percent to $3,379,000 compared to the previous corresponding period.
Nuheara said the customer receipts primarily came from direct-to-customer sales of its personal hearing devices, including its Iqbuds Max hearing and sound filtering earbuds.
The company said it had cash and cash equivalents of $4,431,000 at June 30, 2020 compared to $3,220,000 at June 30, 2019.
Nuheara fell 0.3 cents or 7.3 percent to 3.8 cents with 9.15 million shares traded.

## BIOXYNE

Bioxyne says receipts from customer for the 12 months to June 30, 2020 were up 60.9 percent to $2,817,000 compared to the previous corresponding period.
Bioxyne said the receipts came from sales of its probiotics and fortified milk formulas for nutrition and immune support, including Lactobacillus fermentum VRI-003.
The company said it had cash and cash equivalents of $1,748,000 at June 30, 2020 compared to $1,769,000 at June 30, 2019.
Bioxyne fell 0.2 cents or 14.3 percent to 1.2 cents.

## MGC PHARMACEUTICALS

MGC says it receipts from customers for the year to June 30, 2020 were up 27.3 percent to $2,112,000 but had one quarter of cash at June 30.
MGC said its receipts came primarily from its medical marijuana-based products including Cannepil and MXP100 for epilepsy.
The company said it had cash and cash equivalents of $1,877,000 at June 30, 2020 compared to $2,355,000 at June 30, 2019.
MGC fell 0.2 cents or 8.7 percent to 2.1 cents with 4.7 million shares traded.

## OPTISCAN IMAGING

Optiscan says its receipts from customers for the year to June 30, 2020 were $1,329,000 with receipts for the three months to June 30 of $755,000.
Biotech Daily was unable to find a corresponding Appendix 4C report.
Last year, Optiscan said its revenue for the 12 months June 30, 2019 was $1,041,679 (BD: Aug 30, 2019).
Today, the company said it receipts came sales of its confocal microscope imaging technology, including a milestone payment from the Jena, Germany-based Carl Zeiss Meditec of EUR100,000 ($A171,042) (BD: May 4, 2020).
Optiscan said it had cash and cash equivalents of $526,000 at June 30, 2020 compared to $1,752,440 at June 30, 2019.
Optiscan was up 0.1 cents or 2.2 percent to 4.6 cents.

## CORRECTION: DORSAVI

Yesterday's edition said that due to the Covid-19 pandemic the physical therapy industry patient volumes had reduced by "up-to 70 percent".
In fact, the volumes had been reduced by up to 60 percent and had returned to 70 percent of pre-pandemic levels.
Dorsavi noted that along with sales returning, it had moved to a recurring revenue system which was positive, along with a reduction in costs.
The mistake was made by the Thursday Appendix 4C sub-editor who was under immense pressure to edit other news items.
Unusually, the editor will take the fall for this one.
We apologize unreservedly to Dorsavi and our readers for the error.
Dorsavi was up 0.1 cents or 4.35 percent to 2.4 cents with 1.25 million shares traded.

## RHYTHM BIOSCIENCES

Rhythm says it hopes to raise $3,627,000 in a three-for-five, non-renounceable, pro-rata rights offer at six cents a share, in addition to its $2.4 million placement.
Last week, Rhythm said it had raised $2.4 million in a placement at six cents a share (BD: Jul 23, 2020).
Today, the company said that shareholders would be eligible to subscribe for three new shares for every five shares held at the record date of July 28, the offer would open on July 31 and close on August 28, 2020.
The company said the funds would be used for research and development, clinical trial recruitment, regulatory applications, marketing and business development, and general working capital.
Rhythm fell 0.1 cents or 1.2 percent to eight cents.

## BTC HEALTH

BTC says it has sold its accounting subsidiary Bio101 Group Pty Ltd for $500,000, which it purchased for $100,100 in 2016 (BD: Jul 4, 2016).
BTC did not disclose to whom Bio101 was sold.
BTC executive chairman Dr Richard Treagus said the company's vision was "to become a leading supplier of innovative medical products in Australia and New Zealand".
"The sale of Bio101 is a logical step enabling BTC health to focus future investment on its products businesses to maximise growth for shareholders," Dr Treagus said.
BTC fell 0.5 cents or 4.8 percent to 10 cents.

## AZURE HEALTH TECHNOLOGY

Azure says it has completed the study protocol for an 80-patient, phase II trial of IVB001 for non-alcoholic fatty liver disease and non-alcoholic steatohepatitis.
Azure said the randomized, double-blind, placebo-controlled study at eight sites in Australia would analyze the efficacy and safety of the tocotrienol-based IVB001 using its trans-mucosal delivery platform.
The company said the active pharmaceutical ingredient was a formulation of delta tocotrienol which a previous phase Ia trial had shown be efficiently delivered trans-mucosally, achieving improved bioavailability compared to orally administered tocotrienols when patients were in the fasted state.
Azure said 60mg doses of IVB001 or placebo would be self-administered sublingually three times a day for 24 weeks.
The company said that the primary endpoints would be safety and efficacy measured by mean change from baseline to week-24 of hepatic steatosis, with one secondary endpoint the measure of change from baseline in liver elasticity as measured by Fibroscan at week-12 and weel-24.
Azure said the study would be powered for statistical significance.
Azure is a public unlisted company.

## EMVISION MEDICAL DEVICES

Scott Kirkland says he has increased but been diluted in Emvision from 3,695,000 shares (6.42%) to 3,748,400 shares (5.34%).
Last week, Emvision said it had "binding commitments" to raise $9 million in a placement at $1.42 a share (BD: Jul 24, 2020).
Today, the Brisbane, Queensland-based Mr Kirkland said that between December 20 and 21, 2018 he bought 53,400 shares for $16,197, or an average of 30.3 cents each, and was diluted on July 30, 2020.
Emvision was up 5.5 cents or 3.3 percent to $1.705.

## EMVISION MEDICAL DEVICES

Ryan Laws and Skaha Investments Pty Ltd says they have increased their shares but been diluted below five percent in Emvision and ceased their substantial holding.
The Perth-based Mr Laws and Skaha said that between December 19, 2018 and June 4, 2019 they bought 100,000 shares for $32,403 or 32.4 cents a share, but were diluted on July 7, 2020 following the capital raising (see above).

## SIMAVITA

Simavita says Tiga Trading and Fifty-Second Celebration have increased their holdings while Chevron Corporation and Dussman Group have reduced.
Simavita said it had issued 590,087,778 Chess Depositary Interests (CDIs) following the approval of the conversion of 2019 convertible notes at a meeting in June.
Simavita said that the Melbourne-based Tiga Trading Pty Ltd had increased its holding from 55,612,657 shares (9.86%) to 196,557,190 shares (17.03%).
The company said Melbourne's Fifty-Second Celebration Pty Ltd had become substantial through the conversion with 183,721,717 shares or 15.92 percent of the company.
Simavita said the Perth-based Chevron Corporation Pty Ltd and associates had increased but been diluted from 72,178,317 shares (12.80%) to 104,763,526 shares (9.08) percent.
The company said that the Melbourne-based Dussman Group's 115,769,031 shares had been diluted from 20.53 percent to 10.03 percent.
Simavita said that Jolimont Lodge Pty Ltd and Powell Superannuation Fund, Robert Hutchison and Mary Ann McKenzie and Inspiration Superannuation Fund, George Tauber Management Pty Ltd and Thirty-Fifth Celebration Pty Ltd had ceased their substantial shareholding in the company.
Simavita was up 0.2 cents or 9.1 percent to 2.4 cents.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

McRae Investments Pty Ltd and McRae Technology say their 24,343,954 shares in Neuroscientific have been diluted from 33.08 percent to 31.06 percent.
The Perth-based McRae Investments and McRae Technology said that on July 27, 2020 their shares were diluted following the release of shares, performance shares and options from escrow.
Earlier this month, Neuroscientific says it would release 19,349,506 shares, 36,000,000 options expiring March 7, 2021, and 2,800,000 performance shares from ASX escrow on July 27, 2020.
Neuroscientific was unchanged at 23 cents.

## VOLPARA HEALTH TECHNOLOGIES

Volpara says shareholders at its annual general meeting will vote to issue 852,200 options to director Karin Lindgren and chief executive officer Dr Ralph Highnam.
Vopara said it proposed issue Ms Lindgren 450,000 options, exercisable at $1.84 each by January 31, 2027, as part of her non-executive director remuneration package.
The company said it would issue 402,200 options, exercisable at $1.30 each by April 1, 2027 to Dr Highnam in place of his entitlement to a cash bonus, subject to performance criteria.
Volpara said shareholders would vote on the re-election of directors Ms Lindgren, John Diddams and Roger Allan, to approve amendments to previous grants of options, the ratification of shares in the April placement and the fixing of the company's auditor.
The meeting will be held at Level 14, Simpl House, 40 Mercer St, Wellington Central, Wellington on August 19, 2020 at 12pm (NZST).
Volpara was up two cents or 1.5 percent to $1.34.

## ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

Anteris says it has notes recent enquiries about unusual trading patterns in its shares over recent weeks.

Anteris said it was not aware of any information that has not been announced to market which, if known by some in the market, could explain the reason for the unusual trading patterns and decline in the company share price.

The company said it was in compliance with ASX Listing Rule 3.1.

Anteris said it had “engaged external advisers to assist with analyzing share transactional data”.

The company said it had “consulted with the Australian Securities Exchange and will be consulting with [the Australian Securities and Investments Commission]”.

Earlier this month, the Hong Kong-based Star Bright with Constellation Immunotherapy said it reduced its substantial holding in Anteris from 21.61 percent to 12.35 percent, selling shares at $5.66 a share, having previously bought shares at the equivalent of $10.00 to $30.00 before the 100-to-one consolidation (BD: Feb 26, Jul 17, 2020).

Also, this month, Constellation Immunotherapy, Everbest City and Fung Yuen Wong (Everbest Group) ceased their substantial holding, also selling the shares at a loss, having bought 326,951 shares at $5.65 a share and selling 32,648 shares at $4.315 a share (BD: Jul 21, 2020).

Last week, Anteris said it was not aware of information it has not announced which, if known, could explain the reason for the sale of shares by substantial shareholders, but did not say whether it had been queried by the ASX (BD: Jul 27, 2020).

All three announcements were made either just before or after the market closed at 4pm.

For the month of July, Anteris has fallen 31.0 percent from $5.00 a share to $3.45 a share.

In 2018, Star Bright acquired 19.99 percent of the then Admedus, intending to acquire 60 percent of the Prof Ian Frazer Coridon vaccine business for $18 million and appoint Admedus chief executive officer Wayne Paterson chairman of the vaccine business for five years (BD: Apr 27, 2018).

Anteris fell a further 17 cents or 4.9 percent to $3.28.