# Biotech Daily

Wednesday July 12, 2017

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: DIMERIX UP 20%, PSIVIDA DOWN 16%**

*** DIMERIX: 'DMX-200 SAFETY, MEANINGFUL KIDNEY DISEASE EFFICACY'**

*** BARD1 PLACES $1.1m, PLAN FOR $1m MORE**

*** US PATENT FOR PATRYS 3E10 CANCER TREATMENT**

*** ATCOR SIGNS 3 TRIAL CONTRACTS WORTH $800k**

*** US FDA APPROVES OVENTUS O2VENT W**

*** NOVITA RAISING $3.5m, TO BUY NEWLY FOR $1m SCRIP**

*** TARGET TO SELL NUHEARA IQBUDS**

*** CRYSTAL AMBER TAKES 46% OF GI DYNAMICS**

## MARKET REPORT

The Australian stock market fell 0.96 percent on Wednesday July 12, 2017 with the ASX200 down 55.1 points to 5,673.8 points.

Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and one was untraded. All three Big Caps fell.

Dimerix was the best on good news (see below), climbing as much as 40 percent to 1.4 cents, before closing up 0.2 cents or 20 percent at 1.2 cents with 73 million shares traded.

Cellmid and Prana climbed eight percent or more; Starpharma was up 4.2 percent; Acrux improved 3.8 percent; Pharmaxis rose 1.96 percent; with Cyclopharm, Ellex, Mesoblast, Osprey and Pro Medicus up by less than one percent.

Psivida led the falls, down 40 cents or 16 percent to $2.10 with 23,321 shares traded, followed by Prima down 10 percent to 2.7 cents with 5.1 million shares traded.

Genetic Signatures and ITL lost seven percent or more; Oncosil fell five percent; Benitec, Compumedics and Reva were down more than three percent; CSL, Impedimed, Nanosonics, Orthocell, Polynovo and Sirtex shed more than two percent; with Actinogen, Avita, Clinuvel, Cochlear, Neuren and Resmed down by one percent or more.

DIMERIX

Dimerix says its 27-patient, phase IIa trial of DMX-200 for chronic kidney disease has met its safety primary endpoint and shown efficacy in a meaningful number of patients.

Dimerix said that six patients in the proof-of-concept, dose-escalation trial achieved a greater than 50 percent reduction in proteinuria, or blood in their urine, beyond that achieved with the highest dosage of current standard of care therapy.

The company said that 45 percent of patients had been granted ongoing treatment under a special access scheme on the recommendation of their advising physician, confirming confidence in the treatment.

Dimerix said it would progress with the design for the planned 30-patient, phase IIb DMX-200 study, expected to start by the end of 2017.

In 2015, Dimerix (then Sun Biomedical) said DMX-200 was a combination of irbesartan and propagermanium for chronic kidney disease, with irbesartan used to treat hypertension and nephropathy in type II diabetic patients and propagermanium used for hepatitis B in Japan and as a dietary supplement in the US (BD: Sep 14, 2015).

Today, Dimerix said there were no serious safety concerns observed in patients on irbesartan when treated with 10mg to 80mg of propagermanium three times daily.

The company said three patients withdrew from the study, with anaemia secondary to a gastrointestinal bleed, depression and progression of renal disease.

Dimerix said that a 50 percent or greater increase in proteinuria in the follow-up period after the last dose, suggested that DMX-200 had a possible benefit in slowing the disease progression in these patients.

Co-principal investigator Prof David Packham said the data was “very encouraging”.

“DMX-200 and its combination with existing best therapy appears safe and was well tolerated,” Prof Packham said.

“An incremental 50 percent fall in proteinuria is a high bar to set in studies of this type and the observation of this efficacy endpoint in 25 percent of the patients certainly warrants further clinical investigation in a larger, more targeted, population,” Prof Packham said.

Dimerix chief executive officer Kathy Harrison said “the clinically meaningful reductions in proteinuria are highly encouraging and support the rationale behind the program,” Ms Harrison said.

“Given this is a hard-to-treat patient group, we now have a very strong indication that the treatment is having a significant impact in slowing the progression of chronic kidney disease,” Ms Harrison said.

Ms Harrison said that chronic kidney disease was a complex and silent epidemic driven by increasing and affecting 1.7 million Australians and 26 million Americans each year.

“It is a progressive disease, which means that without treatment, a patient’s proteinuria levels will tend to get worse over time,” Ms Harrison said. “If we can further demonstrate in our studies that DMX-200 reduces those levels and prevents progression to the need for blood dialysis, we will have a very viable therapy and a huge leap forward in treatment options for patients over the current highest standard of care.”

Dimerix said the primary endpoint was the safety and tolerability of propagermanium, over a range of doses when added to stable treatment of the angiotensin receptor type 1 antagonist, irbesartan, in patients with proteinuria.

The company said that all patients were on a stable dose of irbesartan for three or more months prior to enrolment, and received additional escalating doses of propagermanium from 10mg to 80mg three times a day at four-week intervals unless proteinuria fell to within normal limits, and remaining on their maximum dose for a further eight weeks.

Dimerix climbed as much as 40 percent to 1.4 cents, closing up 0.2 cents or 20 percent at 1.2 cents with 73 million shares traded.

## BARD1 LIFE SCIENCES

Bard1 says it has raised $1,097,326 through the placement of 137,165,811 shares at 0.8 cents a share.
Bard1 said it hoped to raise a further $1 million through a share purchase plan at the same price.
Last week, the company said that the funds would be used to fund ongoing research and development programs, commercial initiatives and for general working capital purposes (BD: Jul 5, 2017).
Bard1 was up 0.1 cents or 11.1 percent to one cent.

## PATRYS

Patrys says the US Patent and Trademark Office has granted a patent relating to its 3E10 cancer treatments, triggering a $180,000 payment to Nucleus Therapeutics.
Patrys said the patent, entitled 'Cell-penetrating anti-DNA antibodies and uses thereof to inhibit DNA repair' covered 3E10 variants, including PAT-DX1 until April 2031.
The company said the patent protected the method of use of the Deoxymab 3E10 family.
Patrys chief executive officer Dr James Campbell said the first US patent protecting the use of Deoxymab 3E10 was "a significant milestone for Patrys, and secures the development and commercialisation rights for PAT-DX1".
Dr Campbell said that Patrys had begun pre-clinical studies, secured non-dilutive funding and was "building a strong position at the forefront of nuclear-penetrating antibody therapeutics".
Patrys said the patent grant initiated the second tranche payment to the original shareholders of Nucleus Therapeutics of $180,000 in Patrys shares at 0.5174 cents a share, with a third and final $180,000 tranche triggered on the first dosing of a patient in a phase I trial with therapeutics from the Deoxymab family.
Patrys was unchanged at 0.6 cents.

## ATCOR MEDICAL

Atcor says it has signed three new trial contracts worth $800,000 to use its Sphygmocor central blood pressure systems and clinical trial support services.
Atcor said the deals were with unnamed pharmaceutical companies, of which two were existing clinets and one was a new customer.
The company said the trials would be conducted in the US, Europe and Japan and run for 12 months to 17 months.
Atcor said that if the two phase II trials were successful they were expected to open a larger opportunity when they progressed to phase III.
Atcor chief executive officer Duncan Ross said the contracts supported the company's diversification into new therapeutic areas.
"They include a trial in the acute coronary syndrome field, which is a condition brought on by the sudden reduction of blood to the heart, and a trial in the heart failure field," Mr Ross said.
Atcor said that heart failure was a chronic and increasingly costly disease and a growing focus for its Sphygmocor technology, with Sphygmocor specified for additional heart failure trials with other companies, and negotiations underway.
Atcor said that Sphygmocor had been used in drug trials for inflammatory disorders and type 2 diabetes, further expanding the addressable market.
Atcor was unchanged at five cents.

## OVENTUS MEDICAL

Oventus says it has US Food and Drug Administration has provided 510k clearance for its O2Vent W for snoring and mild to moderate obstructive sleep apnoea.
Oventus said that with Modern Dental signed as its US distribution partner and appliances with mandibular advancement mechanisms cleared for sale, it would focus on ramping up US sales.
The company said that the O2Vent W was a winged, or dorsal flex, appliance with first sales planned by October and expected to ramp up from October 2017.
Oventus said the winged device would allow dentists to deliver appliances with the Oventus airway technology.
The company said that up to 18 million US adults had sleep apnoea with at least 80 percent outside care or not treated effectively with other therapies.
Oventus chief executive officer Neil Anderson said the company had “the right product mix and right distribution partner to accelerate our launch into the lucrative US market”.
The company said that its positive airway pressure connection, which was in development, would be compatible with the O2Vent W for low pressure combination therapy.
Oventus was up three cents or 9.2 percent to 35.5 cents.

## NOVITA HEALTHCARE

Novita says it will acquire Newly Pty Ltd, has raised $2.5 million in a placement at three cents a share and hopes to raise a further $1 million in a rights issue.
Novita said that it would pay Newly $1.0 million in shares upfront and a deferred cash earn-out of four times profit before tax for the 12 months to December 31, 2019.
The company said that Newly was “an innovative online marketplace connecting care and support professionals with people and organisations in need”.
Novita said that Newly was “an innovative and scalable technology platform that provides an enhanced recruitment solution for the aged [and] community and disability care sector … [and had] one of the largest database of carers in Australia, and has established relationships with major care providers nationally”.
Novita said it could potentially extend the application of Newly’s technology across the broader community care spectrum to provide services complementary to its Tali training system for diagnosing and treating developmental disabilities, including autism (BD: Oct 12, 2015) .
Novita executive chairman Iain Kirkwood said the acquisition was “consistent with Novita’s renewed strategic focus on exploring innovative and cutting-edge aged and community care technology opportunities”.
The company said that the one-for-six rights issue record date was July 18, it would open on July 19 and close on August 18, 2017.
Novita was unchanged at 3.2 cents with 2.5 million shares traded.

## NUHEARA

Nuheara says that the based Target Corporation has begun sales of its Iqbuds sound filtering and hearing earbuds through its website: www.target.com.
Nuheara was up 0.3 cents or 3.1 percent to 10 cents with 19.4 million shares traded.

## GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 252,504,725 shares (45.26%) to 258,559,341 shares (46.35%).

The London and Guernsey Island-based Crystal Amber Fund said that between June 29 and July 10, 2017 it bought 6,054,616 shares for $421,944 or 6.97 cents a share.

GI Dynamics was untraded at seven cents.