Biotech Daily

Wednesday July 12, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: COMPUMEDICS UP 16%; EMVISION DOWN 9%**

*** PHARMAXIS: 5 OF 9 PXS-5505 MYELOFIBROSIS PATIENTS IMPROVE**

*** HERAMED PLACEMENT RAISES $2.6m**

*** RACE PAYS ARDENA $1.5m FOR RC220 MANUFACTURE**

*** PROF MARK DAWSON WINS $1.1m LEUKAEMIA GRANT**

*** LITTLE GREEN $1.6m FRENCH MARIJUANA TRIAL SUPPLY**

*** RECCE TAKES $802k RADIUM RDTI LOAN**

*** EYE CO WINS FLUDRO-CORTISONE MACULAR DISEASE US PATENT**

*** IMAGION PLEADS SCHULTZ TO ASX 89.5% PRICE QUERY**

*** PHILLIP HAINS REPLACES CHIMERIC DIRECTOR LESLIE CHONG**

*** AEGROS APPOINTS DR RANJEET AJMANI ASIA CEO**

*** GI DYNAMICS 'REBRANDS AS MORPHIC MEDICAL, ENDOBARRIER RESET'**

MARKET REPORT

The Australian stock market climbed 0.38 percent on Wednesday July 12, 2023, with the ASX200 up 26.8 points to 7,135.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and three were untraded. All three Big Caps fell.

Compumedics was the best, up 2.5 cents or 15.6 percent to 18.5 cents, with 80,964 shares traded. Cynata and improved more than four percent; Genetic Signatures, Mesoblast and Pharmaxis were up more than three percent; Actinogen rose 2.6 percent; Antisense, Dimerix, Polynovo and SDI were up more than one percent; with Cyclopharm, Opthea, Pro Medicus, Proteomics and Telix up by less than one percent.

Yesterday's 15 percent best, Emvision, led the falls, down 12 cents or 9.2 percent to $1.18, with 37,784 shares traded. Universal Biosensors lost 8.3 percent; 4D Medical and Kazia fell more than six percent; Immutep, Next Science and Paradigm were down more than three percent; Volpara shed 2.8 percent; Alcidion, Cochlear, Nanosonics and Neuren were down more than one percent; with Avita, Clinuvel, CSL and Resmed down by less than one percent.

PHARMAXIS

Pharmaxis says five of nine patients in its open-label, phase II trial of PXS-5505 for bone marrow cancer myelofibrosis have shown improved bone marrow fibrosis.

Pharmaxis said the trial aimed to test if PXS-5505 was safe and effective as a monotherapy in patients intolerant, unresponsive or ineligible for treatment with approved Janus kinase inhibitor drugs.

The company said 21 patients were enrolled in the cohort expansion phase of the study, with 10completing 24 weeks of treatment and 10 had dropped out due to a lack of clinical response or adverse events unrelated to the drug.

Pharmaxis said that of the five patients who improved, four showing stable haematological parameters, with three reporting symptomatic improvement.

The company said that symptoms for four of the 10 patients improved in symptom scores of more than 20 percent, with seven patients showing a stable or improved haemoglobin count.

Pharmaxis said that eight of the 10 patients had stable or improved platelet counts, of which three patients had grade four, or potentially life-threatening, thrombo-cytopaenia at baseline.

The company said it would present the final results from the cohort at the American Society of Hematology Conference later this year.

Pharmaxis said it had applied to the US Food and Drug Administration for the next study cohort in combination with a Janus kinase (JAK) inhibitor, with an expected start scheduled “later this year”.

The MD Anderson Cancer Centre’s Prof Dr Lucia Masarova said “PXS-5505 continues to show not only an excellent safety profile but also promising clinical activity”.

“The effect on bone marrow fibrosis is particularly exciting for a disease like myelofibrosis, where despite numerous years of research, we do not have any effective anti-fibrotic drugs,” Dr Masarova said.

“It is encouraging to see that majority of 10 patients who completed 24 weeks of therapy also had improvements of symptoms and more importantly, stable or improved blood counts; including in those patients with severe thrombocytopenia,” Dr Masarova said.

“These results support plans to continue clinical investigation of the agent, including combinations with JAK inhibitors where the lack of overlapping haematological toxicity would make PXS-5505 an ideal add-on candidate,” Dr Masarova said.

Pharmaxis chief executive officer Gary Phillips said the results from the trial with an oral lysyl oxidase enzyme (LOX) inhibitor showing improvements in fibrosis grade in bone marrow biopsies “corroborate the findings of the trial of our topical LOX inhibitor in established skin scars where we saw a 30 percent reduction in collagen in skin biopsies after only three months treatment”.

“Further to the published pre-clinical research showing disease modification in several different indications, this is a mechanism which is now proven to be anti-fibrotic in patients,” Mr Phillips said.

“The excellent safety profile of PXS-5505 makes it an ideal candidate to combine with JAK inhibitors, the current standard of care in myelofibrosis,” Mr Phillips said.

“We anticipate that the impact on bone marrow fibrosis and other clinical parameters from the antifibrotic and intracellular effects of [lipoxygenase] inhibition should lead to improved outcomes for patients,” Mr Phillips said.

“We look forward to FDA feedback on our protocol and expect to start recruitment of this next cohort later this year,” Mr Phillips said.

Pharmaxis was up 0.2 cents or 3.85 percent to 5.4 cents with 1.4 million shares traded.

HERAMED

Heramed says it has raised $2.58 million in a placement at 7.0 cents a share, a 6.67 percent discount to its last closing price.
Heramed said that investors would receive one option for every two shares bought, exercisable at 12 cents a share within three years of issue.
The company said the proceeds would fund the commercialization of its Heracare foetal heart rate monitor platform in the US and Australia, help build inventory and refine the Heracare platform as well as integrating new customers.
Heramed said Clarity Capital Advisors Pty Ltd was the lead manager to the issue.
Heramed was unchanged at 7.5 cents.

RACE ONCOLOGY

Race says it will pay Ardena Holding NV about $US1 million ($A1.5 million) to provide good manufacturing practice-standard RC220 intravenous bisantrene.
Last week, Race said it would replace its RC110 with RC220 bisantrene (BD: Jul 7, 2023).
Today, the company said the Ghent, Belgium-based Ardena was a contract manufacturing organization providing sterile injectable products for clinical development.
Race said the five-year deal strengthened its existing manufacturing and would serve as a primary source for European Union-compliant supplies of RC220 for European studies, as well as providing a back-up source for the US and Australia.
The company said the initial development budget was about $US1 million and Ardena was expected to provide the first EU and international compliant good manufacturing product supplies by the end of 2023.
Race fell 4.5 cents or three percent to $1.465.

THE LEUKAEMIA FOUNDATION

The Leukaemia Foundation says the Peter MacCallum Cancer Centre's Prof Mark Dawson has won a $US750,000 ($1,113,651) Translational Research Program grant.
The Leukaemia Foundation said that Prof Dawson was a clinician-scientist and would receive the funds over three years from July 2023 to June 2026.
The organization said that it was part of a "collaboration to fund breakthrough research … to overcome acquired resistance to anti-cancer cellular immunotherapies" such as chimeric antigen receptor (Car) T-cell therapy" with the Rye Brook, New York-based Leukemia & Lymphoma Society andMelbourne's Snowdome Foundation.
The Leukaemia Foundation said Prof Dawson's team had developed pre-clinical models that simulate resistance to Car-T-cell therapy and Prof Dawson aimed "to uncover the intrinsic properties of cancer cells that enable them to evade new cellular therapies, paving the way for the design and development of novel therapeutic approaches".

LITTLE GREEN PHARMA

Little Green Pharma says it has won a commercial tender to supply $1.6 million of its marijuana cannabidiol (CBD) oil to a French medicinal marijuana trial.
Little Green said it would supply more than 85 percent of the trial's marijuana.
The company said the French Government had selected it to supply the 3,000-patient trial at $77.00 a bottle.
Little Green was up one cent or 5.3 percent to 20 cents with 1.1 million shares traded.

RECCE PHARMACEUTICALS

Recce says Radium Capital has loaned it $801,604 against its expected Federal Government Research and Development Tax Incentive.
Recce did not disclose commercial terms of the loan.
Recce was unchanged at 63 cents.

EYE CO PTY LTD

Eye Co says the US Patent and Trademark Office has granted a patent for its lead compound fludro-cortisone acetate to modulate retina receptors for macular disease.
Eye Co said the patent, titled 'Medical device and pharmaceutical composition for treatment of an eye disease or condition' would protect its intellectual property until 2039.
The company said the patent recognized the ability of fludro-cortisone acetate to module the activity of gluco-corticoid and mineralo-corticoid receptors in the retina, in various packages, including as dry powder and as a suspension in hemp seed oil.
Eye Co said it had applied for patents for high potential indications for fludro-cortisone acetate in the treatment of macular disease, with a patent for the treatment of geographic atrophy already approved in Australia and other jurisdictions expected in coming months.
Eye Co is a private company.

IMAGION BIOSYSTEMS

Imagion has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 89.5 percent from 1.9 cents a share on Monday July 10 to 3.6 cents today and noted a "significant increase" in the trading volume from July 11 to today.
Imagion closed up half a cent or 20.8 percent at 2.9 cents with 45.9 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says non-executive director Ms Leslie Chong has resigned to focus on her duties as Imugene chief executive officer with Phillip Hains to fill the casual vacancy
Chimeric said that Ms Chong had been a director since August 2020.
The company said that Mr Hains was the Chimeric chief financial officer and joint company secretary and principal of Melbourne's CFO Solution.
Chimeric was up 0.1 cents or 2.4 percent to 4.2 cents.

AEGROS

Aegros says it has appointed Dr Ranjeet Ajmani as its Asia chief executive officer.
Last year, Aegros founder and chair Prof Hari Nair told Biotech Daily that with co-founder and managing-director John Manusu, formerly of Nusep, the company expected to have the same blood fractionation output in Australia as CSL (BD: Nov 25, 2022).
Today, Aegros said Dr Ajmani was known as "the father of India's blood plasma industry" and had a reputation across South-East Asia for his academic, commercial, and policy work setting up blood transfusion and blood plasma collection networks and infrastructure.
The company said Dr Ajmani held a Doctor of Philosophy from Mumbai's Indian Institute of Technology.
Aegros is a public unlisted company.

GI DYNAMICS

GI Dynamics says it will “rebrand” as Morphic Medical and rename its Endobarrier duodenal sleeve for obesity and type 2 diabetes as Reset.

Last year GI Dynamics says it has approval for a 100-patient, clinical trial in India for its Endobarrier duodenal sleeve for type 2 diabetes and obesity (BD: Feb 10, 2022).

In 2020, GI Dynamics said it would delist from the ASX but remain focused on attaining a Conformité Européenne (CE) mark for Endobarrier with clinical trials in India and the US (BD: Jul 20, Nov 6, 2020).

In 2015, the company closed its 500-patient Endobarrier trial due to bacterial liver infections in five of the 325 enrolled patients and a later analysis showed that it failed to meet safety and efficacy endpoints (BD: Mar 6, 2015, Mar 15, 2016).

In 2011, GI Dynamics initial public offer to list on the ASX raised about $80 million of the hoped for $95 million at $1.10 a share to develop its Endobarrier weight loss treatment (BD: Aug 15, 30, 2011).

In 2020, the company’s extraordinary general meeting voted 99.6 percent in favor to delist from the ASX, when it was trading around 0.2 cents (BD: Jun 22, Jul 20, 2022)

Today, GI Dynamics said the “transformative shift reflects the evolving landscape of the industry and Morphic Medical's commitment to driving innovation in patient care”.

The company said the rebranding carried “two powerful connotations” with Morphic Medical's devices “empowering patients to ‘morph’ into a healthier state, effectively combating diabetes and obesity to improve metabolic health and management of their disease”.

GI Dynamics said it had “undergone a significant evolution, aligning its strategy and approach with the current understanding of the disease”.

“The Reset product is designed to help patients' metabolic system re-establish itself and its ability to benefit from diet and exercise therapies, and as indicated by its name, offers patients a fresh start in navigating their journey with type 2 diabetes,” the company said.

GI Dynamics chief executive officer Joseph Virgilio said the company was “thrilled to unveil Morphic Medical and Reset as we embark on this exciting chapter in our company's history”.