



Biotech Daily

Wednesday March 9, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: MESOBLAST UP 17%; AMPLIA DOWN 10%**
- * **PARADIGM: 'FINAL USPTO REJECTION NOT FINAL'**
- * **EYE CO: OMEGA-3,6 FOR AMD TRIAL**
- * **EMYRIA STARTS EMD-RX5 PHASE I RECRUITMENT**
- * **BRANDON RENAMES MRCF 'BRANDON BIOCATALYST'**
- * **KORDA MENTHA TO LIQUIDATE PALLA PHARMA**
- * **ADALTA RECEIVES 2nd TRANCHE OF \$4m VICTORIA LOAN**
- * **REGAL TAKES 17% OF OPTHEA**
- * **L1 CAPITAL REDUCES TO 8.4% OF ANTERIS**
- * **FIDELITY TAKES 9.6% OF MEDIBIO**
- * **EMVISION APPOINTS 3 ADVISORS**

MARKET REPORT

The Australian stock market was up 1.04 percent on Wednesday March 9, 2022, with the ASX200 up 72.7 points to 7,053.0 points. Twenty-eight of the Biotech Daily Top 40 stocks were up, eight fell, three traded unchanged and one was untraded.

Mesoblast was the best on no news, up 17.5 cents or 17.0 percent to \$1.205, with five million shares traded. Immutep improved 8.3 percent; Actinogen and Telix climbed more than seven percent; Both Micro-X and Prescient were up 6.45 percent; Compumedics and Polynovo were up more than five percent; Atomo, Emvision, Imugene, Neuren, Opthea, Patrys and Resonance rose four percent or more; Antisense and Impedimed improved more than three percent; Cynata and Medical Developments and Pro Medicus climbed more than two percent; Genetic Signatures, Next Science, Orthocell, Paradigm, Pharmaxis and Proteomics were up more than one percent; with CSL, Kazia and Nanosonics up by less than one percent.

Amplia led the falls, down 1.5 cents or 10 percent to 13.5 cents, with 171,030 shares traded. Alcidion, Oncosil, Resmed, Starpharma and Volpara shed more than two percent; Avita lost 1.2 percent; with Clinuvel, Cochlear and Universal Biosensors down by less than one percent.

[PARADIGM BIOPHARMA](#)

Paradigm says a final rejection from the US Patents and Trademarks Office is 'not final' as stated in a research note from stockbrokers Morgans.

Paradigm said that the Morgans research note, titled 'Non-intellectual Property', implied that a 'final rejection' from the US Patents and Trademarks Office (USPTO) in relation to the application for a patent, titled 'Treatment of Bone Marrow Pathologies with Polysulfated Polysaccharides' was final, and "fail[ed] to reflect the accurate patent process which allows for continued interaction with the USPTO over the coming months".

The company quoted FB Rice consulting partner Paul Whenman saying that "once a final rejection issues, an applicant has a number of possible avenues to continue the prosecution of an application".

"Paradigm intends to request continued examination for this patent which is considered additive to their [intellectual property] portfolio," Mr Whenman said.

Paradigm chair Paul Rennie said that a final rejection was "a frequent occurrence in US patent prosecution, which lead to further strategies to amend claims and continue the prosecution".

"Paradigm has previously received final rejections for other patents including our heart failure application which received a final rejection but subsequently obtained the grant of two US patents," Mr Rennie said. "We therefore do not view the rejection of this patent as material to our overall IP strategy."

"It is important however, to address the incorrect claims in the recent research note from Morgans, who made no attempt to verify their information with Paradigm or a patent expert prior to publication," Mr Rennie said.

A copy of the Morgans research note seen by Biotech Daily said that although the rejection could be appealed "we view the loss of critical [intellectual property] protections as likely to curb partnering appetite and potential quantum of partnership deal metrics which forms a major aspect of our valuation".

The research note reduced the target price from \$1.29 to 79 cents a share.

"With formal [intellectual property] protection appearing shaky, we view the remaining bastion of commercial protection surrounding the asset is a long-term exclusive supply agreement with the only FDA-approved supplier of the compound and potential short-term exclusivity post marketing approval, if achieved," the research note said.

"However, supply aside, we believe the asset is increasingly unattractive from a partnering standpoint with pharma typically partnering to gain access to [intellectual property] rather than guarantee of supply, at least not to the scale which informed our prior assumptions," the research note said.

Paradigm said the Morgans report dismissed the importance of the exclusive supply agreement for pentosan polysulfate sodium (PPS) with Bene Pharmachem.

The company said that the report's analyst "apparently believes that PPS could be readily sourced and authorized for human use".

Paradigm said it had previously discussed the difficulty generic manufacturers faced with the PPS molecule with an identical fingerprint to the Bene PPS registered with the US Food and Drug Administration.

"There is only one FDA-approved manufacturer of PPS, Bene Pharmachem GmbH," the company said, adding that it had exclusive, global supply agreements for injectable PPS for multiple indications extending for 25 years post first marketing approval and an ongoing collaboration agreement with Bene for product-related development support for meeting regulatory milestones and development of PPS for new indications and second-generation molecules.

Paradigm was up 1.5 cents or 1.5 percent to \$1.04 with two million shares traded.

EYE CO PTY LTD

Eye Co says it has ethics approval for a first-in-human trial of omega-3 and omega-6 to prevent the progression of age-related macular degeneration (AMD).

Eye Co said the study would determine whether “a simple adjustment to dietary intake can positively impact this condition before irreversible damage occurs to the retina”.

The company said it would undertake a 12-month study in early stages of the condition using calibrated doses of omega oils with anti-inflammatory ratios, to begin this year.

The company said omega-3 and omega-6 were the two essential poly-unsaturated fatty acids required for human biological function, with omega-3 promoting the production of anti-inflammatory signaling molecules and omega-6 promoting the production of inflammatory molecules, and it had filed patents in relation to its omega oils technology.

Eye Co is a private company.

EMYRIA

Emyria says it has begun recruiting 12 volunteers for a phase I trial comparing the safety and bioavailability of its marijuana-based EMD-RX5 to Epidyolex.

Emyria said Epidyolex was the only cannabidiol (CBD)-only medicine registered with the Australian Therapeutic Goods Administration and the US Food and Drug Administration.

The company said that it expected dosing by the end of this month, with a pivotal phase III trial to follow, pending successful ethics approval.

Emyria managing-director Dr Michael Winlo said “Emyria’s first registration program is aimed at developing an over-the-counter, schedule 3 treatment targeting the symptoms of psychological distress”.

Emyria was up two cents or 7.3 percent to 29.5 cents.

BRANDON CAPITAL

Brandon Capital says it has renamed its Medical Research Commercialisation Fund (MRCF) as the ‘Brandon Biocatalyst’.

Brandon Capital managing-partner and Biocatalyst chief executive officer Dr Chris Nave said “the new name better captures the intent, energy and momentum of this truly unique collaboration, which is to leverage and coordinate Australia and New Zealand’s globally competitive biomedical capabilities to catalyze the next generation of biotech companies and create new treatments for patients”.

Brandon Capital said that since the fund’s inception in 2007, it had invested in more than 50 biotechnology companies, including Vaxxas for needle-free vaccines, Aravax working on a treatment for peanut allergies and Ena Respiratory developing a nasal spray to boost the immune system to fight respiratory infections.

The company said Brandon Biocatalyst had brought together more than 50 leading medical research institutes and hospitals from Australia and New Zealand, Australian superannuation funds, the Australian and New Zealand governments, as well as state territory governments.

“When we were starting out in 2007, the MRCF was a working title,” Dr Nave said.

“Like all start-ups, we were singularly focused on getting the collaboration up and running, and not thinking too much about branding,” Dr Nave said.

“For this reason, the MRCF name stuck and while it has served us well, everyone acknowledges that it is a bit of a mouthful and can be confused with other medical initiatives with similar acronyms,” Dr Nave said.

Brandon Capital is a private company.

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRIES ENTERPRISES)

Korda Mentha administrators Craig Shepard and Bryan Webster says the second meeting of creditors resolved to wind up Palla Pharma.

Korda Mentha said that Mr Shepard and Mr Webster were appointed liquidators.

Last week, Korda Mentha said the administrators “do not anticipate a return to shareholders” following the liquidation of the company, with “priority employee creditors” to receive 100 percent, with unsecured creditors to receive between six and 84 percent of what they were owed by the company (BD: Mar 3, 2022).

Today, the liquidators said it would rely on exemptions for financial reporting obligations and an annual general meeting.

“We anticipate providing a further update to the market, including any potential return to shareholders, over the coming weeks once the asset realization process has progressed,” Korda Mentha said.

ADALTA

Adalta says it has received a second, \$1.6 million tranche under the Victorian Government’s R&D Cash Flow Loan Initiative.

Last year, Adalta said it had a \$4.0 million facility with Treasury Corporation of Victoria and a first tranche of \$2.4 million was expected (BD: Sep 20, 2021).

Today, the company said the funds would be used for an inhaled form of AD-214 for trials in idiopathic pulmonary fibrosis patients and for development of its internal pipeline.

The company said that repayment of the Facility was timed to coincide with receipt of its Federal Research and Development Tax Incentive, expected by October 31, 2023.

Adalta was unchanged at 7.3 cents.

OPTHEA

Regal Funds Management says it has increased its substantial holding in Opthea from equivalent to 59,294,620 shares (17.06%) to 63,815,800 shares (18.13%).

Sydney’s Regal Funds said it held 40,751,384 (11.58%) Australian shares and 2,883,052 American depository shares, each representing eight Australian shares.

The company said it bought and sold shares between June 21, 2021 and March 4, 2022, with the largest purchase 1,500,000 shares for \$1,725,000 or \$1.15 a share.

Regal said on February 25, 2022 it bought 2,921 American depository shares for \$US17,803, or \$US6.09 (\$A8.44) per American depository share, equivalent to eight Australian shares or \$A1.055 a share.

Opthea was up 3.5 cents or 4.35 percent to 84 cents.

ANTERIS TECHNOLOGIES

L1 Capital says it has reduced its substantial holding in Anteris from 1,163,391 shares (9.93%) to 1,137,029 shares (8.39%).

The Melbourne-based L1 said it sold 26,362 shares on March 7, 2022, but did not specify the consideration as required under the Corporations Act 2001.

Anteris was up \$1.33 or 7.7 percent to \$18.53.

MEDIBIO

Fidelity says it has increased its substantial holding in Medibio from 121,928,459 shares (7.77%) to 215,314,445 (9.56%) shares.

The Hong Kong-based Fidelity said that it bought 31,716,505 shares on market at 0.9 cents and 1.0 cents a share on April 1, 2021 and on March 4, 2022, bought 61,669,481 shares in the entitlement offer at 0.5 cents a share.

Last week, Medibio said it and CPS Capital “mutually agreed that the [underwriting] agreement be terminated in light of the escalation of hostilities between Russia and Ukraine” (BD: Mar 2, 2022).

Last December, Medibio said it hoped to raise \$5.7 million through a \$2.25 million placement at 0.5 cents a share and a \$3.4 million one-for-three rights offer at the same price, with the entitlement offer, pending shareholder approval, expected to be underwritten with the underwriting terms “yet to be finalized” (BD: Dec 15, 2021).

Medibio was unchanged at 0.4 cents with 11.9 million shares traded.

EMVISION

Emvision says it has appointed Prof Geoffrey Donnan, Prof Stephan Davis and Dr Angela Dos Santos to its clinical advisory board.

Emvision said that Prof Donnan was a former president of the World Stroke Organization, former chair of the World Congress of Neurology and was currently the co-chair of the Australian Stroke Alliance.

The company said that Prof Davis was the University of Melbourne’s professor of translational neuroscience, director of the Melbourne Brain Centre, a former president of the World Stroke Organization and currently a co-chair of the Australian Stroke Alliance.

Emvision said Dr Dos Santos was Australia's first Aboriginal neurologist with subspecialty training in stroke, and currently works at the Royal Melbourne Hospital, the Alfred Hospital and the Mobile Stroke Unit.

Emvision was up nine cents or 4.8 percent to \$1.96.