



Biotech Daily

Thursday May 12, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: AMPLIA UP 14%; USCOM DOWN 15%**
- * **CSL VIFOR ACQUISITION DELAYED**
- * **MTP CONNECT \$894k FOR ATMO, CORTICAL DYNAMICS, PROTEOMICS**
- * **MTP CONNECT REDI FELLOWSHIPS**
- * **RACE: CALVARY MATER APPROVES ZANTRENE AML, MDS TRIAL**
- * **ENA IN J&J-BARDA 'BLUE KNIGHT' INITIATIVE**
- * **BURNET, ORBIS WORK ON REMOTE, RURAL DIAGNOSTICS**
- * **RHYTHM FINAL TGA COLOSTAT FILING**
- * **NEUROTECH SCRAPS WASHOUT FOR NTI164 AUTISM TRIAL**
- * **INCANNEX COMPLETES APIRX DEAL**
- * **INCANNEX APIRX SHARES, DIRECTORS STOCK EGM**
- * **JM FINANCIAL TAKES 15.4% OF MACH7**
- * **RESMED LOSES SLEEP HEAD JIM HOLLINGSHEAD**

MARKET REPORT

The Australian stock market fell 1.75 percent on Thursday May 12, 2022, with the ASX200 down 123.7 points to 6,941.0 points. Six of the Biotech Daily Top 40 stocks were up, 27 fell and seven traded unchanged. All three Big Caps fell.

Amplia was the best, up 1.5 cents or 14.3 percent to 12 cents, with 208,242 shares traded. Dimerix climbed 11.1 percent; Avita and Nova Eye were up more than eight percent; with Polynovo and Starpharma up by more than one percent.

Uscom led the falls, down 1.5 cents or 15 percent to 8.5 cents, with 87,882 shares traded. Telix lost 11 percent; Paradigm fell 8.6 percent; Clinuvel, Impedimed, Kazia, Micro-X and Universal Biosensors were down six percent or more; Atomo, Imugene, Neuren, Opthea and Proteomics fell five percent or more; Cynata, Nanosonics and Orthocell fell more than four percent; Actinogen, Genetic Signatures, Prescient, Pro Medicus and Resonance were down more than three percent; Cochlear, Immutep, Mesoblast, Resmed and Volpara shed more than two percent; with Antisense, CSL, Cyclopharm and Emvision down by one percent or more.

CSL

CSL says its acquisition of the St Gallen, Switzerland-based Vifor Pharma AG, expected by June 2022 has been delayed and will “take a few more months”.

Last year, CSL said it would acquire Vifor for \$US12.3 billion (\$A17.2 billion) for its renal disease and iron deficiency expertise (BD: Dec 16, 2021).

In March, CSL said it had received applications for 74 percent of Vifor shares at the close of the main period for the public tender offer, planned to waive the original 80 percent acceptance rate condition and to declare the offer successful” (BD: Mar 4, 2022).

Today, the company said it was “confident of completing its acquisition of Vifor Pharma” but provided no information about the delay.

CSL fell \$5.04 or 1.8 percent to \$271.18 with 859,116 shares traded.

MTP CONNECT, PROTEOMICS INTERNATIONAL LABORATORIES

MTP Connect says it will provide \$893,826 to Atmo Biosciences, Cortical Dynamics and Proteomics International to support medical device development.

MTP Connect said that the funding was through the Federal Government Biomedtech Horizons.

The Federal-funded industry organization said that Melbourne’s Atmo Biosciences Pty Ltd would receive \$343,310 for further development of the its gas capsule through clinical trials “for better diagnosis and treatment of gastrointestinal disorders”

MTP Connect said that the Swinburne University and Perth based Cortical Dynamics Ltd would receive \$137,000 for further development of its Brain anaesthesia response monitor for brain data monitoring and feedback.

In 2011, Cortical Dynamics said it would raise up to \$4 million to list on the ASX to commercialize the monitor (BD: Jun 3, 2011).

In 2018, the BPH Energy 3.6 percent subsidiary said its monitor was being used in trials at an undisclosed Melbourne hospital (BD: Jan 21, 2018).

MTP Connect said that Proteomics would receive \$413,516 for its Promarkerd test for diabetic kidney disease.

Proteomics told the ASX that it would receive \$413,516 from the Federal Government to support domestic manufacturing of its Promarkerd diabetic kidney disease diagnostic.

Proteomics said the funding was awarded by MTP Connect, through the Federal Government’s \$45 million Biomedtech Horizons program, an initiative of the Medical Research Future Fund.

The company said the funds would establish local manufacturing supply chains, quality assurance procedures and support an application for Australian Therapeutic Goods Administration approval of Promarkerd.

Proteomics managing director Dr Richard Lipscombe said the grant would “help our activities towards obtaining Australian Therapeutic Goods Administration approval and registration of Promarkerd under the Medical Benefits Scheme”.

MTP Connect chief executive officer Stuart Dignam said that the Biomedtech Horizons program was “all about supporting the development of the Australian medical device sector”.

“Targeted funding provided through our [Biomedtech Horizons] program addresses gaps in early biomedical and medical technology product development and this round focused on the further development of pre-commercial prototypes entering human clinical trials,”

Mr Dignam said.

Proteomics fell six cents or 5.7 percent to 99 cents.

MTP CONNECT

MTP Connect says 18 researchers, clinicians and professionals have won placements under Researcher Exchange and Development within Industry (Redi) fellowship program. MTP Connect said that the 18 fellowships were from New South Wales, Queensland, South Australia, Victoria and Western Australia and would be working for up to 20-months with small and medium companies in Australia and Europe.

The Federal-funded industry organization said that the Redi Fellowship program provided financial support to Australian and/or multi-national companies “to bring the best Australian talent in-house to work on priority research projects”.

MTP Connect chief executive officer Stuart Dignam said that connecting researchers, clinicians and sector professionals with industry was “critical for the growth of Australia’s medical products sector”.

“It is excellent to see the Redi initiative going from strength to strength, ramping up Australia’s [biotechnology] sector with new fellowships and programs to improve workforce skills and boost medical research commercialization and entrepreneurship in Australia,” Mr Dignam said.

The complete list of 2022 Redi fellows is available at:

https://www.mtpconnect.org.au/Story?Action=View&Story_id=474.

RACE ONCOLOGY

Race says it has approval for a 60-patient, phase Ib/II dose expansion trial of Zantrene, or bisantrene, for extra-medullary acute myeloid leukaemia and myelo-dysplastic syndrome. In April, Race said it had ethics approval and was seeking a site-specific ‘research governance office’ approval from the Calvary Mater Newcastle Hospital in New South Wales (BD: Apr 6, 2022).

Today, the company said the hospital’s research governance office had approved its application to begin the trial, and a site meeting had been scheduled for May 31, 2022 to induct staff to the site and prepare for recruitment.

Race said the trial was expected to take up to 40 months, with full patient recruitment expected over the next 18 months.

Race fell seven cents or 3.5 percent to \$1.92.

ENA RESPIRATORY

Ena says it is the first Australian company to be accepted into the Johnson & Johnson US Biomedical Advanced Research and Development Authority Blue Knight initiative.

Ena said that the Blue Knight program would provide scientific and technological support and mentorship from BARDA and Johnson & Johnson Innovation’s JLABs for the development of its INNA-051 antiviral nasal spray.

In March, Ena said it had dosed the first of a 123-person, phase IIa, randomized, double-blind, placebo-controlled challenge trial of INNA-051 as a prophylaxis for influenza (BD: March 16, 2022).

Today, Ena chief executive officer Dr Christophe Demaison said the company looked forward to “working alongside BARDA, industry leaders and other innovative companies with the aim to address emerging health threats and better protect our global community against infectious diseases”.

Ena is a private company.

BURNET INSTITUTE

The Burnet Institute says it will work with the Auckland, New Zealand-based Orbis Diagnostics to develop and deliver diagnostics to remote and rural communities. The Burnet said the partnership would combine its research with Orbis' point-of-care diagnostics to develop a suite of finger-prick blood tests for infectious disease and liver health.

Burnet diagnostics initiative director Jennifer Barnes said that "a key challenge to delivering health care in rural communities is access".

"Removing the waiting time for diagnostic test results will be a major step towards helping address this challenge," Ms Barnes said.

"Our focus has been on the development of lateral flow tests, but the partnership with Orbis Diagnostics will allow us to develop our biomarkers into multiple test formats and reach more communities in need," Ms Barnes said.

Orbis chief executive officer Damian Camp said his company's diagnostic technology platform was designed "to provide quick and accurate information about a person's health, at point-of-need".

"The partnership will involve developing a suite of diagnostic screening products," Mr Camp said.

"The type of tests offered will be based on high-need but could span analyzing a person's liver function right through to testing for sexually transmitted diseases," Mr Camp said.

"Through our Covid-19 immunity test, we've successfully demonstrated our technology has huge potential to run a number of diagnostic tests at the point of care," Mr Camp said. Mr Camp said the partnership intended to begin a pilot program in a remote location in the next 12 months.

"With comparable accuracy to the complex tests available in medical labs, each Orbis device is capable of testing up to eight people at a time and reporting results within 15 minutes from a finger-prick sample, making it a robust, cost-effective, scalable, and practical solution to support delivery of rural health services," Mr Camp said.

RHYTHM BIOSCIENCES

Rhythm says it has submitted the final Australian Therapeutic Goods Administration filing for its Colostat blood test for colorectal cancer screening.

Last year, Rhythm said the TGA had accepted its manufacturer's evidence documentation, with the next step filing for an Australian Register of Therapeutic Goods (ARTG) listing (BD: Sep 14, 2021).

Today, Rhythm said the completed filing was "a significant regulatory milestone".

The company said approval of the filing would allow the commercial sale of Colostat for clinical use in Australia.

Rhythm said it expected an answer from the TGA within three to six months.

The company said that in the meantime, it was focused on executing a number of key technical, administrative and logistical activities that would support market entry, both domestically and internationally, in late 2022.

Rhythm managing-director Glenn Gilbert said the company targeted Colostat revenues in late 2022.

"We are very close to being in a unique position to transform and revolutionize the colorectal diagnostics market with our lifesaving cancer detection technology," Mr Gilbert said.

Rhythm fell one cent or 0.8 percent to \$1.20.

NEUROTECH INTERNATIONAL

Neurotech says it has modified its phase I/II study of NTI164 for autism to accommodate requests for ongoing patient treatment at Melbourne's Monash Children's Hospital. Last year, Neurotech said it had begun a 20-subject, phase I/II study of NTI-Dolce medical marijuana for children aged five to 17 years old with autism spectrum disorder, and that the trial included a four-week washout (BD: May 5, 2021).

Today, the company said that following a "significant number of requests" from patients' parents and caregivers, the study design had been modified to allow ongoing treatment of patients with NTI164.

Neurotech said it expected efficacy results in June, and a phase II/III trial was scheduled to begin by October 2022.

Neurotech was up 0.1 cents or two percent to 5.1 cents.

INCANNEX HEALTHCARE

Incannex says it has a share sale and purchase agreement with the Scottsboro, Alabama-based medical marijuana company Apix Pharmaceuticals.

In March, Incannex said it intended to acquire Apix for \$US93.3 million (\$A124.6 million) in scrip (BD: Mar 24, 2022).

Today, the company said Apix shareholders would be issued 218,169,506 shares at 57.3 cents a share, the price agreed at the signing of the binding terms sheet in March.

Incannex said completion of the proposed acquisition was subject to shareholder approval.

The company said Apix shareholders had entered a 12-month voluntary escrow deed restricting the disposal of any interest in the shares from completion.

Incannex managing-director Mr Joel Latham said the acquisition "presents us with clear long and short-term opportunities for significant value growth".

"Several drug candidates have shortened regulatory pathways to break into areas of patient need representing very large global markets," Mr Latham said.

"These candidates are our initial development priority," Mr Latham said.

"Incannex's strong cash position allows us to pursue these near-term product opportunities at the same time as moving at pace to develop the Incannex combination drug candidates," Mr Latham said. "Once the acquisition of Apix has been finalized, Incannex will have many diverse projects under development."

Incannex was up 3.5 cents or 9.6 percent to 40 cents with 9.7 million shares traded.

INCANNEX HEALTHCARE

Incannex says its extraordinary general meeting will vote to issue 218,169,506 shares to Apix shareholders and 16.8 million shares and options to its managing-director and chair. Incannex said shareholders would vote to issue \$124.6 million in scrip to acquire Apix, as well as 5,600,000 shares and 5,600,000 options to managing-director Joel Latham as part of his 2022 and 2023 remuneration packages, vesting in three equal tranches with the options exercisable at 26 cents, 31 cents, 35 cents respectively within three years.

The company said investors would vote to issue 2,800,000 shares and 2,800,000 options to chair Troy Valentine, vesting and exercisable under the same conditions.

Incannex said shareholders would vote on the election of director George Anastassov, and the approval of the company's performance rights plan.

The meeting will be held virtually on June 9, 2022 at 11am (AEST), and be available at

www.investor.automic.com.au.

[MACH7 TECHNOLOGIES](#)

JM Financial says it has increased its substantial holding in Mach7 from 26,238,486 shares (14.35%) to 36,699,105 shares (15.37%).

The Melbourne-based JM said that in more than 150 transactions between May 28, 2020 and May 6, 2022, it bought, sold, and transferred shares, with the largest single purchase on June 17, 2020, of 6,911,834 shares for \$4,700,047, or 68 cents a share.

Mach7 fell 2.5 cents or 4.5 percent to 53 cents.

[RESMED](#)

Resmed says its head of sleep and respiratory care Jim Hollingshead has resigned, effective from May 5, 2022, "to pursue an opportunity with a new employer".

Resmed said that chief operating officer Rob Douglas had been appointed interim head of sleep and respiratory care until a permanent replacement could be found.

Resmed fell 75 cents or 2.6 percent to \$27.67 with 1.5 million shares traded.