



Biotech Daily

Wednesday April 21, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ALTERITY UP 33%; ACTINOGEN DOWN 14%**
- * **VICTORIA \$50m FOR mRNA RESEARCH, MANUFACTURE**
- * **EMYRIA RAISES \$5m**
- * **NUHEARA STARTS ELITE EARBUD HEWLETT PACKARD PRODUCTION**
- * **FACTOR THERAPEUTICS: FROM WOUNDS TO LIMESTONE MINING**
- * **INCISIVE WINS FEDERAL \$1m FOR BLUECHECK FOR TOOTH CARIES**
- * **TELEX PHASE I JAPAN TRIAL: TLX250-CDX SAFE, TOLERABLE**
- * **BIOXYNE PLEADS SCHULTZ TO ASX 50% QUERY**
- * **IMUGENE: PFS ENDPOINT MET IN PHASE II HER-VAXX TRIAL**
- * **ECOFIBRE: HEMP RESEARCH COMPLETED 15 MONTHS EARLY**
- * **ANALYTICA REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **INVESTORS MUTUAL REDUCES TO 7.5% IN MAYNE**
- * **FOUNDER DR MEL BRIDGES, PARMA REDUCES TO 7% OF ANATARA**
- * **FREEMAN ROAD BELOW 5% OF RESAPP**

MARKET REPORT

The Australian stock market fell 0.29 percent on Wednesday April 21, 2021, with the ASX200 down 20.4 points to 6,997.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell and 10 traded unchanged. All three Big Caps were up.

Alterity was the best on more ATH434 mouse data, up one cent or 33.3 percent to four cents, with 365.05 million shares traded. Imugene improved 8.1 percent; Antisense and Osprey climbed more than five percent; Pharmaxis was up 3.7 percent; Cyclopharm and Resonance rose more than two percent; Cochlear, CSL, Optiscan, Resmed and Telix were up more than one percent; with Clinuvel, Neuren and Proteomics up less than one percent.

Actinogen led the falls, down 0.8 cents or 13.8 percent to five cents, with 55.3 million shares traded. Impedimed lost 11.5 percent; Amplia fell 7.7 percent; LBT was down 6.1 percent; Medical Developments fell five percent; Nova was down three percent; Immutep, Starpharma and Volpara shed more than two percent; Avita, Kazia, Oncosil, Opthea and Universal Biosensors were down more than one percent; with Nanosonics, Paradigm and Pro Medicus down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says it will invest \$50 million for messenger ribonucleic acid (mRNA) manufacturing technology and research.

The State Government said the facility would “provide certainty of supply of new vaccines and lifesaving treatments in Australia”.

A media release from Acting Premier James Merlino said that following the Federal Government identifying onshore production of mRNA vaccines as a national priority, the Victoria Government would provide \$50 million to establish mRNA vaccine and therapeutic manufacturing in Melbourne, through partnerships with Victorian universities, researchers and manufacturing companies.

The State Government said that Victoria was “ideally placed to lead in mRNA manufacturing and the production of mRNA vaccines and therapeutics”.

The Victoria Government said it would work Monash University, the University of Melbourne, the Doherty Institute and other research institutes to develop the first mRNA manufacturing capability in the Southern Hemisphere.

The media release said that mRNA vaccines were “a promising alternative to traditional vaccines because of their high efficacy, capacity for rapid development, low-cost manufacture and safe administration”.

The Government noted “the success of the mRNA [Sars-Cov-2] vaccines from Pfizer Biontech and Moderna which are manufactured in Europe and the US”.

The State Government said that developing mRNA manufacturing capability locally in Victoria would provide “vaccine security, ensuring manufacturing could be contracted locally to avoid global supply chain issues and creating a more robust defence against future pandemics”.

The media release said mRNA and other forms of RNA nanomedicines could be used in the treatment of cancer, rare diseases, cellular engineering and protein-replacement therapy and the investment would accelerate RNA-based projects and new treatments.

The State Government said it welcomed the opportunity to work with the Federal Government to secure mRNA manufacturing capability and further investment in mRNA vaccines in Victoria might be considered through the Breakthrough Victoria Fund.

Mr Merlino said it was “vital that we can develop and manufacture mRNA vaccines and treatments locally to ensure we have vaccine security here ... across our region”.

The media release said that Victoria had the strongest mRNA capability in the country and the \$50 million would give researchers support to expand that capability.

The media release did not specify whether a dedicated mRNA facility would be built and a response had not been received at the time of publication.

EMYRIA

Emyria says it has raised \$5 million in a placement at 17.5 cents a share to sophisticated and strategic investors, with \$800,000 corner-stoned by lead manager Sixty Two Capital. Emyria said that one unlisted attaching option would be issued for every two new shares acquired, exercisable at 35 cents each within two years.

The company said that the placement would advance its trials of EMD-003 and EMD-004, define US Food and Drug Administration regulatory pathways, initiate scoping of a psychedelic-assisted trial, support data analysis and intellectual property filings.

Emyria said it had increased its cash position to about \$8.5 million.

The company said that Sixty Two Capital would be issued five million unlisted options at the same price and would receive a six percent capital raising fee

Emyria fell half a cent or 2.6 percent to 19 cents with 1.1 million shares traded.

NUHEARA

Nuheara says it has begun manufacturing its Elite wireless earbuds to be an option bundled with Hewlett-Packard notebook computers.

Nuheara said it expected the first shipment of earbuds to Hewlett-Packard to begin in "early May 2021".

Nuheara chief executive officer Justin Miller said the company was "incredibly proud to be working and developing products for [Hewlett-Packard], a global technology leader".

"Nuheara's co-development of the new HP Elite wireless earbuds has seen this new product delivered, from concept to mass production, in record time," Mr Miller said.

Mr Miller said he expected "the strengthening of this partnership over the next three years to continue the supply of innovative audio solutions to [Hewlett-Packard's] customers".

Nuheara fell 0.1 cents or two percent to 4.9 cents with 14.1 million shares traded.

FACTOR THERAPEUTICS (FORMERLY TISSUE THERAPIES)

Factor says it has a term sheet with the Power Lime Inc which has an option to acquire land in the US considered "prospective for high calcium limestone".

Factor said that, pending due diligence, shareholder and regulatory approvals the Early County, South Georgia-based Power Lime would be acquired and become a wholly owned subsidiary of Factor, which would become a resources company.

Factor said it had sought advice from the ASX on relevant Listing Rule matters and it would make a presentation at the annual general meeting scheduled for May 28, 2021.

The then Tissue Therapies was developing Vitrogro as a wound treatment for venous ulcers, claiming "excellent results" ($p < 0.0001$) from a 30-patient study, but was unable to obtain Conformité Européenne (CE) mark approval, expected since 2012, but with repeated delays the company lost the services of chief executive officer Dr Steven Mercer (BD: Jul 9, 2008; Sep 30, 2010; Sep 30, 2011; Apr 7, 2015).

The company said that 12-year chair Roger Clarke also resigned in 2015 later saying that it could be two more years to European approval (BD: May 25, Jun 1, 2015).

Tissue Therapies appointed Dr Christian Behrenbruch as an executive director with chair Dr Cherrell Hirst, renamed Vitrogro as VF001, renamed the company Factor Therapeutics and began a 168-patient, phase II, US trial of VF-001 for venous leg ulcers (BD: Oct 12, Dec 17, 2015; Apr 29, 2016; Apr 7, 2017).

In 2018, Factor fell 97.3 percent to 0.2 cents on news that its 157-patient, phase II trial of VF001 for venous leg ulcers "failed to meet all endpoints" (BD: Nov 14, 2018).

Effectively, the company has been a shell looking for an acquisition since the trial.

Today, Factor Therapeutics said that director Dr Christian Behrenbruch would not seek re-election and would retire at the meeting, after five and a half years with Factor and it had appointed its company secretary since 2016, Melanie Farris, as a non-executive director, effective from April 20, 2021.

The company said that Ms Farris had experienced in governance and corporate operations and a non-executive director with more than 13 years' experience.

Factor said Ms Farris was previously a director of, and company secretary for, Invion and chair of Synapse Australia, and was currently Telix's company secretary.

The company said that Ms Farris held a Bachelor of Communication and a Graduate Diploma in Applied Corporate Governance.

Factor said that from August 1, 2020, directors would defer 50 percent of fees until a transaction was completed and the company had re-complied with Listing Rules 1 and 2 to the satisfaction of the ASX.

Factor was in a suspension and last traded at 0.5 cents.

INCISIVE TECHNOLOGIES PTY LTD

Melbourne's Incisive says it has received \$1 million from the Department of Industry, Science and Technology for its Bluecheck diagnostic for early-stage tooth caries. Incisive said it was the only one of 12 companies to receive the maximum amount of \$1 million for an 18-month program from the Accelerating Commercialisation program.

The company said the funding would enable clinical studies evaluating the use of Bluecheck "as an effective, fast, and inexpensive diagnostic tool for early-stage caries". Incisive said Bluecheck was a dental paint applied to the teeth to help detect problems early so that preventive measures can be used, including remineralization and better patient education.

The company said that tooth caries was "the most prevalent chronic disease globally and disproportionately targeting underserved populations".

Incisive said that the Bluecheck technology was sourced from the University of Melbourne and uses selected proteins which have a propensity to seek out degraded tooth enamel, allowing the identification of caries earlier than x-ray or and visual inspection.

The company said Bluecheck would reduce the use of routine drill-and-fill invasive procedures, significantly lowering cost and burden.

Incisive said it held patents in all the major markets and planned to apply for US registration by early 2022, along with in the EU, Asia and Australia.

Incisive is a private company.

TELIX PHARMACEUTICALS

Telix says the phase I component of its phase I/II trial of TLX250-CDx for renal cancer imaging in Japan, has met its study objectives of safety and tolerability.

Last year, Telix said that its up-to 40-patient, phase I/II, multi-centre study of its zirconium-based diagnostic TLX250-CDx had dosed the first patient in Japan and the study aimed to confirm the safety, tolerability, sensitivity and specificity of positron emission tomography imaging with TLX250-CDx to detect clear cell renal cell cancer. (BD: Aug 18, 2020).

Today, the company said its zirconium dosing and comparison in Japan (Zirdac-JP) study had shown safety and tolerability with no adverse effects or serious adverse effects.

Telix said the study on six patients with an identified indeterminate renal mass was conducted at Yokohama City University hospital and all patients were dosed with TLX250-CDx and multi-time-point positron emission tomography (PET) imaging.

Telix said the radiation dosimetry of the whole body and specific organs did not show any difference between Caucasian and Japanese patient populations.

Telix chief medical officer Dr Colin Hayward said the company was "highly encouraged" by the safety and tolerability profile as well as the comparability of the dosing and pharmacology between Japanese and Caucasian patient populations.

Dr Hayward said the company would consult with the Japan regulator on the design of the next stage of development, with the objective of bridging to the phase III Zircon study.

Telix was up five cents or 1.3 percent to \$3.96 with 595,719 shares traded.

BIOXYNE

Bioxyne 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 0.9 cents or 50 percent from 1.8 cents to 2.7 cents today April 21, 2021 and noted a "significant increase" in the trading volume.

Bioxyne closed up half a cent or 31.25 percent to 2.1 cents with 7.9 million shares traded.

IMUGENE

Imugene says it has reached the clinical endpoint of progression-free (PFS) survival for 24 events in its phase II trial of the HER-Vaxx cancer immunotherapy for gastric cancer.

In January, Imugene said it had completed recruitment in the 36-patient, phase II trial of HER-Vaxx with chemotherapy for gastric cancer (BD: Jan 17, 2021).

Today, the company said the data from the 24 events would be analyzed and it expected the final progression-free survival read-out "within months".

Imugene said the primary endpoint of the trial was overall survival and a secondary endpoint was progression-free survival.

The company said the study was randomised into HER-Vaxx with standard-of-care chemotherapy and standard-of-care chemotherapy alone and was conducted at multiple sites across eastern Europe and India.

Imugene managing-director Leslie Chong said that the 24 events was a "significant milestone for patients with advanced gastric cancer, following on from the important interim data released in 2020 and new data presented ... earlier this month".

Imugene was up 1.5 cents or 8.1 percent to 20 cents with 53.5 million shares traded.

ECOFIBRE

Ecofibre says it has completed its \$US5 million (\$A6.4 million) hemp-based research and development program "15 months ahead of schedule".

Ecofibre said the program was a multi-year research partnership with Philadelphia's Thomas Jefferson University and was completed early due to "early research success" and commercialization opportunities.

Ecofibre chief executive officer Eric Wang said the program developed key technologies and patents which included hemp-based char or oils and polymers with enhanced properties, high temperature bio-char carbonization and methods for production of hemp-based composites.

The company said it has appointed seven alumni of the University, Jeff Bruner as head of Hemp Black, Mark Sunderland as the chief innovation and sustainability officer, Robin Sheldon as general counsel and company secretary and Tom Carberry as head of merchandising and design.

Ecofibre said it would issue 1,646,116 shares to Thomas Jefferson University for the research and a six-month option for 7,964,581 shares for a total of \$4.3 million.

Ecofibre was up 13 cents or 11.8 percent to \$1.23.

ANALYTICA

Analytica has requested a trading halt "pending an announcement regarding a capital raising".

Trading will resume on April 23, 2021 or on an earlier announcement.

Analytica last traded at 0.5 cents.

MAYNE PHARMA GROUP

Sydney's Investors Mutual says it has reduced its substantial holding in Mayne from 146,034,058 shares (8.70%) to 125,723,514 shares (7.49%).

Investors Mutual said that between March 17, 2020 and April 16, 2021 it bought and sold shares, with the single largest sale 2,530,382 shares for \$1,086,546 or 43 cents a share.

Mayne was unchanged at 46 cents with 7.2 million shares traded.

[ANATARA LIFESCIENCES](#)

Founder Dr Mel Bridges says he has reduced his substantial holding and has been diluted in Anantara from 5,746,844 shares (12.51%) to 4,683,965 shares (6.65%).

Dr Bridges said that through the Capalaba, Queensland-based Parma Corp he bought and sold shares on-market between September 10, 2015 and April 13, 2021 with total sales amounting to 1,105,163 shares for \$310,519 or an average of 28 cents a share, and was diluted in a share plan.

Last year, Anantara said its share plan for \$750,000 had applications for \$2,069,500 and was scaled back to \$1.4 million taking the total raised with the placement to \$3.07 million (BD: Nov 16, 2020).

Anantara was up half a cent or 2.8 percent to 18.5 cents.

[RESAPP HEALTH](#)

Freeman Road says it has ceased its substantial shareholding in Resapp following the sale of shares and dilution in a placement.

Last week, Resapp said it had commitments to raise \$5.5 million through a placement at 5.8 cents a share (BD: Apr 12, 2021).

Today, the Perth-based Freeman Road said that between October 8, 2019 and January 31, 2021 it sold shares, with the single largest sale 1,011,980 shares for \$252,857 or 25 cents a share on January 29, 2020.

Freeman Road said it retained 40,500,000 Resapp shares, which Biotech Daily calculates to be 4.71 percent of the company.

Resapp was up 0.2 cents or 3.8 percent to 5.5 cents with 5.3 million shares traded.