



# Biotech Daily

Monday November 22, 2021

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: ALTERITY UP 8%; USCOM DOWN 8%**
- \* **EBR RAISES \$110m FOR 'WISE' WIRELESS PACEMAKER IPO**
- \* **USCOM 3-FOR-10 RIGHTS ISSUE FOR \$5.2m**
- \* **REDHILL FALLS 27% ON UNDERWRITTEN \$21m RAISE**
- \* **MESOBLAST PAYS HERCULES WITH \$124m OAKTREE LOAN**
- \* **EMYRIA \$5m FROM TATTARANG, DR ANDREW 'TWIGGY' FORREST 7%**
- \* **TOTAL BRAIN LOAN EXTENSION**
- \* **MEMPHASYS: 1<sup>st</sup> FELIX SALE TO CHINA'S DIAGENS FOR IVF**
- \* **ANTERIS IMPLANTS 5 PATIENTS WITH DURAVR VALVE**
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- \* **IMUGENE AGM 56% OPPOSE DIRECTOR DR AXEL HOOS**
- \* **CHIMERIC 17.5% OPPOSE REMUNERATION REPORT**
- \* **PARADIGM: PAUL RENNIE CHAIR, DR DONNA SKERRETT INTERIM CEO**

## MARKET REPORT

The Australian stock market fell 0.59 percent on Monday November 22, 2021, with the ASX200 down 43.4 points to 7,353.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 21 fell and seven traded unchanged.

Alterity was the best, up 0.2 cents or 7.7 percent to 2.8 cents, with 6.4 million shares traded. Starpharma improved 4.85 percent; Cyclopharm climbed 3.8 percent; Cynata and Prescient rose more than two percent; Genetic Signatures, Next Science, Paradigm and Polynovo were up one percent or more; with CSL, Medical Developments, Pro Medicus and Telix up by less than one percent.

Uscom led the falls, down one cent or 7.7 percent to 12 cents, with 188,144 shares traded. Patrys lost 7.1 percent; Imugene and Proteomics fell more than six percent; Actinogen and Dimerix were down more than five percent; Immutep and Resonance fell more than four percent; Universal Biosensors was down 3.2 percent; Antisense, Kazia, Mesoblast and Volpara shed more than two percent; Avita, Clinuvel, Compumedics, Neuren, Orthocell and Osprey were down one percent or more; with Cochlear, Nanosonics, Opthea and Resmed down by less than one percent.

## BRANDON CAPITAL, EBR SYSTEMS INC

Brandon says that EBR Systems Inc has raised \$110 million at \$1.08 a share to list on the ASX on Wednesday under the code EBR and develop its 'Wise' pacemaker.

Brandon said that the funds would enable the Sunnyvale, California-based EBR to complete a pivotal study of the "wireless stimulation endocardially" or Wise "world's first and only" wireless, inside-the-left-ventricle-of-the-heart pacing system for heart failure, targeting a US Food and Drug Administration FDA approval in 2023.

The company said the device was approved for use in Europe and had FDA breakthrough device designation.

Brandon said that EBR had 53 issued US patents and 44 issued patents outside the US for an estimated addressable market of \$US2.1 billion and up to \$US7.1 billion "when extended to other patient groups".

The company said that investors in the offer, including MH Carnegie & Co, Hostplus Superannuation, Telstra Super and Hesta Superannuation, contributed more \$30 million of the funds raised in the offer, which closed in October.

Brandon said that EBR's chair was Allan Will with chief executive officer John McCutcheon.

The company said that many patients with heart failure required cardiac re-synchronization therapy (CRT), which used lead-based cardiac pacing devices to coordinate the beating of the left and right sides of the heart.

Brandon said the Wise device provided a treatment option for patients unable to receive CRT from a traditional lead-based system or were at high risk from an upgrade procedure. "Without effective CRT, these patients suffer poor clinical prognosis, poor quality of life and reduced life expectancy," the company said.

Brandon founding partner Dr Chris Nave said that "EBR's Wise leadless pacemaker technology is one of the most exciting cardiology technologies in development".

"EBR's early clinical data is very promising and for those heart failure patients not able to receive traditional cardiac re-synchronization therapy, it is life changing: the difference between living a normal life as opposed to being constantly short of breath, often housebound and unable to perform simple daily tasks," Dr Nave said.

Brandon said that EBR was holding clinical trials at the Royal Adelaide Hospital, Melbourne's Monash Medical Centre and Sydney's Prince of Wales Hospital, with the first Australian patient implanted in February 2018.

The company said that a clinical study in Australia and Europe was planned for next year to extend the use of the Wise system, in combination with an intra-cardiac pacemaker, to achieve totally leadless CRT as the first and preferred option for heart failure patients.

Bell Potter, Morgans and Wilsons were joint lead managers to the transaction.

## USCOM

Uscom says it hopes to raise \$5.17 million in a three-for-ten non-renounceable rights issue at 11 cents a share and has commitments for about \$2.5 million.

Uscom said that the record date for the rights issue was November 25, with the offer opening on November 29 and closing on December 10, 2021.

The company said that the share price was a 16.67 percent discount to the 30-day volume-weighted average price to the date of the offer.

Uscom said the funds would be used to develop a manufacturing facility in China for its BP+ central blood pressure monitor, support distribution and manufacturing ramp-ups, and provide the company with working capital.

Uscom fell one cent or 7.7 percent to 12 cents.

## REDHILL BIOPHARMA

Redhill fell 27 percent on news of a fully-underwritten public offer to raise \$US15.5 million (\$A21.4 million).

In an announcement titled, 'Redhill Biopharma Announces Pricing of \$15.5 Million Public Offering of American Depositary Shares', the company said it would offer 4.7 million American depository shares (ADSs) but failed to state the price.

Biotech Daily calculates the share price will be about \$US3.30 a share. 14.9 percent below the company's last closing price of \$US3.88 a share.

Biotech Daily asked Redhill what may have caused the share price to a further 14 percent below the approximate offer price.

Redhill chief executive officer Dror Ben Asher replied: "A financing like this requires that all material information be in the public domain and we are always compliant."

The company said that a preliminary prospectus supplement and the accompanying prospectus relating to and describing the terms of the offering will be filed with the SEC and will be available on the SEC's website at <http://www.sec.gov>, but did not provide a specific address.

The preliminary prospectus is available at: <https://bit.ly/3x7zg5K>.

The preliminary prospectus said that on February 22, 2021, Aether Therapeutics Inc "filed a complaint against us in the US District Court for the District of Delaware, alleging that our marketing of the Movantik product infringes US Patent Nos. 6,713,488, 8,748,448, 8,883,817 and 9,061,024 held by Aether Therapeutics".

"Aether has asserted the Aether Patents against other entities previously involved in the marketing of the Movantik product," Redhill said in the prospectus.

"Given the stage of the Aether litigation, we are unable to predict the likelihood of success of the claims of Aether Therapeutics Inc against us or to quantify any risk of loss," the company said.

Redhill said the litigation "could last for an extended period of time and require us to dedicate significant financial resources and management resources to our defense".

"An adverse ruling against us could materially and adversely affect our business, financial position, results of operations or cash flows and could also result in reputational harm," the company said. "Even if we are successful in defending against these claims, the Aether litigation could result in delays in future product developments, reputational harm or other collateral consequences."

The company said it had a collaboration with Cosmo, including a licence with a wholly-owned subsidiary granting "exclusive rights to commercialize Aemcolo" in the US.

Redhill said that the licence provided that, from October 2022, both parties had "the right to terminate the licence agreement unilaterally, subject to certain conditions".

"Cosmo has recently expressed an interest in regaining its rights to Aemcolo from us prior to October 2022 and may, therefore, elect to terminate the licence agreement ... or we may mutually elect to terminate the license agreement sooner," Redhill said. "Subject to and following amendment or termination of the licence agreement, we would no longer be able to commercialize Aemcolo and may never recover the costs we incurred ... [and] any alternative collaboration or licence, if any, could be on less favorable terms to us."

Redhill said it intended to use the offer proceeds to fund its commercialization activities, clinical development programs and for acquisitions and general corporate purposes.

The company said that New York's Cantor Fitzgerald & Co was the sole bookrunner for the offering, and it had granted Cantor Fitzgerald a 30-day option to purchase up to an additional 15 percent of the number of ADSs offered in the public offering.

On the Nasdaq, Redhill fell \$US1.05 or 27.06 percent to \$US2.83 (\$A3.91) with 4,233,692 shares traded.

## MESOBLAST

Mesoblast says funds managed by Oaktree Capital Management LP have refinanced its existing senior debt facility with a \$US90 million (\$A124.1 million) five-year facility.

Mesoblast said it drew the first tranche of \$US60 million on closing, with proceeds to repay the balance of the existing senior debt facility with Hercules Capital Inc.

In 2018, the company said it had a \$US75 million (\$A96.1 million) “non-dilutive, four-year credit facility” with the Palo Alto, California based Hercules Capital at 9.45 percent per annum (BD: Mar 7, 2018).

Today, Mesoblast said that up to \$US30 million could be drawn on or before December 31, 2022, subject to milestones.

The company said the facility had a three-year interest-only period at 9.75 percent per annum, after which 40 percent of the principal amortizes over two years and a final payment would be due in November 2026.

Mesoblast said that Oaktree would receive warrants (options) over 1,769,669 American depositary shares (ADSs) exercisable at \$US7.26 per ADS, a 15 percent premium to the 30-day volume-weighted average price, and within seven years.

Oaktree executive Aman Kumar said his company recognized “the quality of the portfolio and the significant near-term milestones that could help the company successfully commercialize its first product in the US”.

Mesoblast said that Cantor Fitzgerald & Co was the exclusive arranger and financial advisor for the transaction.

Mesoblast fell four cents or 2.3 percent to \$1.68 with 2.5 million shares traded.

## EMYRIA

Emyria says it has raised \$5 million at 25 cents a share from the Dr Andrew ‘Twiggy’ Forrest-controlled Tattarang, which would hold 7.3 percent of the company.

Emyria said that as part of the placement, Tattarang or its nominee would be issued 10,000,000 options exercisable at 40 cents each within two years.

The company said that the funds would be used to accelerate synthetic cannabinoid registration programs with the Australian Therapeutic Goods Administration and US Food and Drug Administration, and advance its 3,4-methylene-dioxy-methamphetamine (MDMA) analogue program with the University of Western Australia

Emyria said it was “the only ASX-listed company that controls patient-treating clinics and a clinical-trial-grade data system and uses these assets to accelerate the development and registration of new drugs, digital technologies and care models”.

The company said that its programs included synthetic cannabinoid-based pharmaceuticals, MDMA-assisted therapy and novel psychedelic drug development.

Emyria was up 6.5 cents or 20 percent to 39 cents with 6.9 million shares traded.

## TOTAL BRAIN

Total Brain says it has repaid \$600,000 of a \$1.8 million, five-month loan and has secured a term extension at the original 12 percent interest rate to March 18, 2022.

In June, Total Brain said it had the unsecured loan from shareholders and a third-party lender (BD: Jun 25, 2021).

Today, the company said all other terms of the loan remained unchanged, with the loan and interest accrued repayable in cash.

Total Brain was up one cent or 9.5 percent to 11.5 cents.

## MEMPHASYS

Memphasys says it has sold its first Felix sperm separation device to the Diagens Biotechnology Co for in-vitro fertilization (IVF) for \$11,000.

Memphasys said it had worked with the Hangzhou, China-based Diagens over the preceding 18 months in gaining access to Chinese reproductive clinics in order to support a submission to the China National Medical Products Administration for fast-track regulatory approval.

The company said the sale of its Felix device was “a pathfinder sale” and Diagens would seek to deliver the platform to a “major Chinese medical research centre”.

Memphasys said that sale was “a major milestone” in receiving revenue from Felix, and entering the Chinese market, the world’s biggest in-vitro fertilization market world.

Memphasys was up half a cent or 4.8 percent to 11 cents with 3.8 million shares traded.

## ANTERIS TECHNOLOGIES

Anteris says it has implanted five of 10 patients with its Duravr transcatheter heart valve for severe aortic stenosis, as part of a study in Tbilisi, Georgia.

Anteris said the study’s two performance endpoints were the correct positioning of the Duravr implant at the proper anatomical location and haemodynamic performance, as well as safety endpoints.

The company said there were no adverse events in the first-in-human procedures

Anteris climbed \$1.12 or 12.6 percent to \$10.00 with 242,677 shares traded.

## CHIMERIC THERAPEUTICS

Chimeric said further pre-clinical data presented in abstracts to the Society for Neuro-Oncology supported the efficacy of its CLTX-Car-T cell therapy for cancer.

Last week, Chimeric said that its scorpion venom-derived chlorotoxin chimeric antigen receptor T-cell (CLTX-Car-T) treatment resulted in stable disease in three of the four patients in its phase I trial.

Today, the company said that magnetic resonance imaging (MRI) data from one patient two months after treatment showed no recurrence of tumor in the left frontal lobe where CLTX-Car-T cells were infused, but “tumor progression occurred in areas away from where the CLTX-Car-T cells were infused ... [suggesting] that the dual routes of administration (intra-tumoral and intra-ventricular) of the CLTX-Car-T cells in dose levels 2 to 4 may provide additional hope for patients”.

Chimeric was up half a cent or 1.7 percent to 29.5 cents with 1.7 million shares traded.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has engaged Imeka for diffusion magnetic resonance imaging of its Emtinb drug candidate for multiple sclerosis and Alzheimer’s disease.

Earlier this month, Neuroscientific said it had hired the Montreal, Québec-based Biospective, Inc. to run its Emtinb multiple sclerosis studies (BD: Nov 2, 2021).

Today, the company said the Sherbrooke Québec-based Imeka would begin work on the same multiple sclerosis program, with a view to widening its use in future clinical studies.

Neuroscientific said that Imeka’s expertise in diffusion magnetic resonance imaging would aid the company in mapping brain microstructures and articulating more precisely the signals of Emtinb’s disease-modifying effect in the brain.

Neuroscientific was unchanged at 35.5 cents.



## RACE ONCOLOGY

Race says research at New South Wales University of Newcastle shows that Zantrene provides protection from anthracycline chemotherapy-induced cell death, in-vitro.

Race said Zantrene, or bisantrene dihydrochloride, would be “fast-tracked” to a phase IIb trial in breast cancer patients at high risk of anthracycline-caused heart damage, in 2022. The company said that the research found that Zantrene was “able to protect heart muscle cells from anthracycline, specifically doxorubicin, induced cell death while improving the killing of breast cancer cells”.

Race said anthracyclines were effective against a broad array of cancers and the clinically most important anthracyclines were doxorubicin, daunorubicin, epirubicin and idarubicin. “While highly effective anti-cancer drugs, the anthracyclines cause serious and permanent damage to the heart in many patients,” Race said.

The study’s co-lead Prof Aaron Sverdlov said that “the concept of potential cancer therapies that are not only non-cardiotoxic but, in fact, cardio-protective has not been evaluated or even entertained, largely due to disease-specific’ approaches in healthcare”. “Our results suggest that Zantrene, an effective anti-cancer medication, can concomitantly provide protection against toxic effects on the heart from one of the most commonly used chemotherapy agents, doxorubicin,” Prof Sverdlov said.

Race was up 39 cents or 11.5 percent to \$3.77 with two million shares traded.

## IMUGENE

Imugene says its annual general meeting voted against the re-election of eight-year non-executive director Dr Axel Hoos, who has ceased to be a director.

Imugene said the resolution for Dr Hoos’s re-election was opposed by 1,055,914,504 votes (55.95%) with 831,444,111 votes (44.05%) in favor.

The company said resolutions to adopt its remuneration report and ratify a previous placement were passed overwhelmingly.

Imugene thanked Dr Hoos “for his contribution to Imugene’s growth and development”.

According to the company’s most recent filing it had 5,687,313,065 shares on issue meaning the vote against Dr Hoos amounted to 18.6 percent of the company, sufficient to requisition extraordinary general meetings.

Imugene fell 3.5 cents or 6.2 percent to 53 cents with 28.6 million shares traded.

## CHIMERIC THERAPEUTICS

Chimeric’s annual general meeting passed all resolutions, but with up to 18.04 percent opposition to the incentive plan and 17.5 percent against the remuneration report.

Chimeric said that 7,528,948 votes (17.46%) opposed the adoption of the remuneration report, but the greatest percentage opposition was against the omnibus incentive plan with 18.04 percent of annual general meeting votes against the plan.

Chimeric said the largest number of dissenting votes was against the issue of options to director Cynthia Elkins with 7,646,079 votes (6.38%) against, with options for director Dr George Matcham passed by a similar majority.

The company’s most recent filing said that Chimeric had 218,217,152 shares on issue meaning that the opposition to Ms Elkins options amounted to 3.5 percent of the shares on issue, not sufficient to requisition extraordinary general meetings.

The election of directors chief executive officer Leslie Chong, Dr Lesley Russell, Ms Elkins and Dr Matcham, the 10 percent placement facility and the issue of options to Jennifer Chow were passed overwhelmingly.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says executive chair Paul Rennie will continue as non-executive chair, with chief medical officer Dr Donna Skerrett appointed interim chief executive officer.

Paradigm said the appointments would take immediate effect and it had begun a search for a chief executive officer to replace Mr Rennie.

Paradigm was up four cents or 1.9 percent to \$2.19.