Biotech Daily

Wednesday December 8, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NOVA EYE UP 15%; STARPHARMA DOWN 5%**

*** ALCIDION RAISES $43.4m; $11.6m TO GO**

*** ORTHOCELL: 'ORTHO-ATI BEATS STEROIDS FOR INJURY'**

*** TRAJAN ACQUIRES LEAP PAL FOR $10.8m**

*** RACE: ZANTRENE PROTECTS HEART MUSCLE, IN-VITRO**

*** EMYRIA SCREENS 1st MDMA BATCH**

*** AVECHO STUDY CHARACTERIZES SOFT-GEL MARIJUANA CBD**

*** STARPHARMA ADDS TO GENENTECH RESEARCH AGREEMENT**

*** TELIX APPOINTS NUCLIBER ILLUCIX SPAIN DISTRIBUTOR**

*** EMVISION RECEIVES $2m FEDERAL R&D INCENTIVE**

*** TOTAL BRAIN TAKES $2m MITCHELL R&D TAX INCENTIVE LOAN**

*** GOODBYE BARD1, HELLO INOVIQ**

*** CHAIR PAUL HOPPER TAKES 23.3% OF CHIMERIC**

*** DIRECTOR MICHAEL STORK DILUTED TO 4.8% IN PATRYS**

*** HONSUE CHO DILUTED TO 22% OF INVION**

*** VISIONEERING LOSES CEO, DIRECTOR DR STEPHEN SNOWDY**

*** LISA AUBERT REPLACES COCHLEAR NORTH AMERICA HEAD TONY MANNA**

*** RESAPP APPOINTS COVID-19 SCIENTIFIC ADVISORY BOARD**

MARKET REPORT

The Australian stock market was up 1.25 percent on Wednesday December 8, 2021, with the ASX200 up 91.5 points to 7,405.4 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 11 fell and eight traded unchanged. All three Big Caps were up.

Nova Eye was the best, up 4.5 cents or 15.25 percent to 34 cents, with 20,580 shares traded. Orthocell climbed 11.65 percent; Mesoblast was up 10 percent; Compumedics improved 9.7 percent; LBT was up 8.4 percent; Prescient rose 7.1 percent; Pharmaxis was up five percent; Alterity and Clinuvel climbed more than four percent; Nanosonics, Pro Medicus and Telix were up more than three percent; Cochlear, Genetic Signatures, Immutep, Medical Developments, Patrys and Universal Biosensors rose more than two percent; Resmed and Volpara were up one percent or more; with Avita, CSL, Opthea and Proteomics up by less than one percent.

Starpharma led the falls, down 5.5 cents or 4.6 percent to $1.145, with 526,625 shares traded. Actinogen and Cynata fell four percent; Osprey lost 3.7 precent; Next Science, Optiscan, Paradigm and Polynovo shed more than two percent; with Cyclopharm, Kazia and Neuren down by more than one percent.

ALCIDION

Alcidion says its placement and institutional rights offer has raised $30.0 million and $13.4 million, respectively, with a further $11.6 million expected in the retail rights offer.
Yesterday, Alcidion said the capital raising at 25 cents a share would fund the GBP30.0 million ($A56.3 million) acquisition of the Newcastle, England-based Silverlink Software for its patient administration systems (BD: Dec 7, 2021).
Today the company said the first two parts of the raising had been completed, with the underwritten retail rights offer closing on December 23, 2021.
Alcidion was in a trading halt at 32 cents.

ORTHOCELL

Orthocell says its 30-patient study shows that Ortho-ATI is “significantly more effective than steroid injection” for rotator cuff tendinopathy with intra-substance tendon tear.
The company said the randomized, multi-center, open-label study was designed to assess autologous tenocyte implantation (Ortho-ATI) compared to the cortico-steroid standard-of-care for patients with rotator cuff tendinopathy with intrasubstance tendon tear.
Orthocell said the 30 patients were verified by magnetic resonance imaging (MRI) with symptoms of more than six months’, who had previously received physiotherapy and with one or more corticosteroid injections were treated.
Orthocell said that at 12 months after Ortho-ATI treatment, 18 of the 19 patients (94.7%) “reported a level of function of the treated shoulder consistent with a successful outcome” after an average of four failed treatments including physiotherapy and steroid injections.
The company said seven out of the 11 (63.6%) steroid participants withdrew early from the study due to treatment failure and six of the seven participants (85.7%) requested and received Ortho-ATI treatment, due to ongoing pain and loss of shoulder function.
Orthocell said the mean American shoulder and elbow surgeons shoulder assessment (ASES) scores “were significantly better in the Ortho-ATI group compared to the steroid group” from one to 12 months ($p < 0.006$ to $p < 0.001$).
Orthocell said the average visual analogue scale (VAS) pain score fell by 3.2 points, from 4.8 pre-treatment to 1.6 at 12 months post-treatment with a continuous and sustained reduction in pain score.
The company said the average VAS pain score was reduced by 0.9 points from 5.2 pre-treatment to 4.3 at 12 months post-treatment with the average VAS pain score improved to 2.8 at three months, but worsened to 4.2 at six months post-treatment.
Orthocell said that the Ortho-ATI group had “significant improvement in shoulder function between six and 12 months post-treatment, [while] the steroid group experienced no meaningful improvement in shoulder function at any time point”.
Orthocell said it was accelerating its US plans with technology transfer, US Food and Drug Administration (FDA) engagement and commercial preparation activities underway to prepare Ortho-ATI for a randomized, controlled study under FDA supervision.
Orthocell managing-director Paul Anderson said the company was “absolutely delighted with the study results for this challenging and debilitating condition which clearly demonstrates that Ortho-ATI is more effective than steroid injection for treatment of rotator cuff tendinopathy with intrasubstance tendon tear”.
“We are now in a very strong position to progress our US commercialization strategy to deliver the first injectable cell therapy in orthopaedics that truly addresses the cause of degeneration and returns patients to full use of their chronically damaged tendons,” Mr Anderson said.
Orthocell was up six cents or 11.65 percent to 57.5 cents with 3.7 million shares traded.

TRAJAN

Trajan says it has acquired Raleigh, North Carolina's Leap Pal Parts and Consumables LLC for $US7.7 million ($A10.79 million).
Trajan said Leap Pal had a team of nine staff and was expected to have a revenue for the year to December 31, 2021 of $US7.74 million and unaudited earnings before interest, taxes, depreciation and amortization (Ebitda) of $US1.04 million.
The company said the transaction would be funded through cash and debt.
Trajan managing-director Stephen Tomisich said the company bought the business of Leap Technologies in 2016.
"Originally Leap Technologies and [Leap Pal Parts] were two parts of one business; the former developing automated workflows and providing the capital equipment solutions, the latter delivering the parts, supplies and consumables to support those platforms," Mr Tomisch said.
"Around 2010, the two were split [and] with the acquisition … Trajan brings the two parts of that business back together again to provide an integrated and streamlined customer support capability," Mr Tomisch said.
Trajan was up 27 cents or 8.4 percent to $3.49.

RACE ONCOLOGY

Race says Zantrene is able to protect heart muscle cells while improving the carfilzomib-mediated killing of cancer cells, in-vitro.
Race said that the pre-clinical heart safety research on Zantrene, formerly known as bisantrene, was led by the New South Wales-based University of Newcastle Prof Aaron Sverdlov and Prof Doan Ngo and found that Zantrene was able to protect heart muscle from carfilzomib, a new class of anti-cancer drug, which induced cell death, while improving the carfilzomib-mediated killing of cancer cells.
Race chief scientific officer Dr Daniel Tillett said the expansion of Zantrene's cardio-protection and anti-cancer synergy beyond the anthracyclines into the completely new drug class of proteasome inhibitors was unexpected.
"This discovery opens new clinical development pathways and partnering opportunities for Zantrene beyond those already identified," Dr Tillett said.
The company said the question whether Zantrene could help prevent cardiac damage caused by other classes of heart damaging cancer drugs had not been addressed previously.
Race said that animal studies would be conducted in 2022.
Race was up 14 cents or 4.5 percent to $3.27 with 441,826 shares traded.

EMYRIA

Emyria says it the Luxembourg-based Eurofins has screened a number of its of 3,4-methylene-dioxy-meth-amphetamine (MDMA) analogues.
Emyria said 66 of 68 compounds from the initial batch passed screening with no evidence of interactions with one or more of the 'anti-targets' which were enzyme or cell receptor interactions associated with unwanted side effects at the test concentrations.
The company said that a second batch of compounds from the original analogue library of more than 100 compounds was being prepared for initial screening.
Emyria said it had filed a patent family supported by the initial screening data but did not disclose details of its patent application.
Emyria was up 2.5 cents or 6.7 percent to 40 cents with 1.1 million shares traded.

AVECHO

Avecho says its 16-volunteer study of two oral doses of its soft gel marijuana-derived cannabidiol (CBD) has characterized the drug's pharmaco-kinetics.
Avecho said that the 75mg and 150mgl doses aligned with the Australian Therapeutic Goods Administration's "down-scheduling of CBD which has specified that future over-the-counter CBD products must have a maximum daily dose of 150mg".
The company said the study was conducted at CMax in Adelaide with subjects receiving both doses over two weeks, with each dose preceded by an overnight fast.
Avecho said the two doses exhibited minor differences in delivery profile, with mean peak plasma concentrations for the 75mg dose appearing two hours after dosing, whereas peak plasma concentrations for the 150mg dose were evident three hours after dosing.
Avecho said the absorption period of the 150mg dose was longer, with cannabidiol detected in the blood one week after dosing with "no adverse events of concern related to the study medication".
Avecho chief executive officer Dr Paul Gavin said "We now understand the absorption profile from both doses of our proprietary CBD soft-gel in humans".
Dr Gavin said the delivery profiles of both doses "could support utility across a range of potential indications, whether they require once per day, or twice per day, dosing".
Dr Gavin said the company's data package included formulation development and animal data on "high purity, synthetic CBD", soft-gel capsule development and manufacturing, ongoing stability and human phase I pharmaco-kinetics.
"We believe this data package will not only support ongoing regulatory and ethics approvals but also heighten interest from potential partners, especially those looking to avoid two years of product development and jump straight into efficacy studies for indications of interest," Dr Gavin said.
Avecho was up 0.2 cents or 15.4 percent to 1.5 cents with 6.35 million shares traded.

STARPHARMA

Starpharma says that under its agreement with Genentech it will design dendrimer-enhanced product drug conjugates and provide them for testing and characterization
Yesterday, Starpharma said it had a research agreement with Roche Group's Genentech for its dendrimer-enhanced product (DEP) conjugates (BD: Dec 7, 2021).
Today, the company said it would receive research fees which were not expected to be material in this phase, and with no material cost to Starpharma, and each party retained ownership of their own background intellectual property.
Starpharma fell 5.5 cents or 4.6 percent to $1.145.

TELIX PHARMACEUTICALS

Telix says it has appointed Madrid's Nucliber Spain as the exclusive distributor of its Illucix prostate cancer imaging kit.
Telix said Nucliber had experience in the supply of gallium generators across Spain and was selected for "its ability to deliver a secure and continuous supply of 68 Gallium necessary for commercial launch in the country".
The company said prostate cancer was the most commonly diagnosed men's cancer in Spain in 2020, with about 34,600 new cases being diagnosed, higher than lung or bowel cancer, and was a leading cause of cancer death in men, with about 137,000 Spanish men living with prostate cancer in 2020.
Telix was up 26 cents or 3.8 percent to $7.16 with 1.1 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has received $1,990,372 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Emvision said the rebate related to research and development expenditure for the year to June 30, 2021.
The company said it had received $180,00 from GE Healthcare under the co-operative research centre (CRC) project program and $30,000 from the Federal Government, with a further $150,000 expected from the Federal Government and $180,000 form GE Healthcare.
Emvision said it had received $1,200,000 from the Australian Stroke Alliance.
Emvision was unchanged at $2.58.

TOTAL BRAIN (FORMERLY BRAIN RESOURCE LIMITED)

Total Brain says it will borrow $2 million from Mitchell Asset Management Pty Ltd against its expected $2.3 million research and development tax incentive.
Total Brain said the loan, through its subsidiary BRC Operations, would accrue interest at 1.1 percent per month with a minimum interest period of three months and repayable by May 31, 2022.
The company said it would also pay establishment costs and legal fees of less than $10,000.
Total Brain said it intended to repay the advanced funds upon receipt of the current year tax incentive refund, expected “early in calendar 2022”.
Total Brain was unchanged at 11 cents.

BARD1 LIFE SCIENCES

Bard1 says it has formally changed its name to Inoviq Ltd and will trade under the ASX code IIQ from tomorrow, Thursday December 9, 2021.
Last year, Bard1 said it acquired Sienna Cancer Diagnostics (BD: Jul 29, 2020).
Today, the company said the name change “better reflects the strategic vision, broader intellectual property assets and expanded product portfolio … since its acquisition of Sienna”.
Bard1 was up one cent or one percent to $1.035.

CHIMERIC THERAPEUTICS

Chimeric chair Paul Hopper says he has increased his substantial holding in the company from 77,777,778 shares (23.18%) to 78,152,778 shares (23.29%).
The substantial shareholder notice said that Mr Hopper previously held 82,386,830 shares (24.92%) but said that 4,609,052 shares had been excluded “as they do not meet the definition of relevant interest”.
Mr Hopper told Biotech Daily that the shares belonged to his four adult daughters.
The substantial shareholder notice said that Mr Hopper bought 375,000 shares on market for 26.25 cents a share.
Chimeric fell half a cent or 1.9 percent to 25.5 cents with 1.5 million shares traded.

PATRYS

Patrys director Michael Stork says he has ceased his substantial shareholding in the company following the dilution of his 98,773,814 shares.
The Kitchener, Ontario-based Mr Stork said the dilution followed share issues by the company between February 17 and December 7, 2021.
Earlier this year, Patrys director Michael Stork and Stork Holdings said their 98,773,814 shares in Patrys had been diluted from 6.91 percent to 5.46 percent, following the company's $4.9 million capital raising (BD: Jan 17, 2021).
Last week, the company said it had raised $7.83 million in a placement and an associated rights issue (BD: Dec 2, 2021).
According to its most recent filing, Patrys had 2,056,722,509 shares on issue and Biotech Daily calculates that Mr Stork's holding amounts to 4.8 percent of the company.
Patrys was up 0.1 cents or 2.8 percent to 3.7 cents with 5.8 million shares traded.

INVION

Honsue Cho and associates say their 1,467,459,930 share-holding has been diluted from 26.01 percent to 22.89 percent.
Last month, Invion said it had commitments to raise $12 million through the issue of 545,454,546 shares in a placement at 2.2 cents a share (BD: Nov 16, 2021).
Invion was unchanged at 1.8 cents with 10.9 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says chief executive officer and executive director Dr Stephen Snowdy has resigned and will leave the company on January 9, 2022.
Visioneering said Dr Snowdy was leaving the company "to pursue an opportunity in oncology, a personal passion for Dr Snowdy and his family".
Visioneering chair Dr David Mazzo said Dr Snowdy had "helmed" the company for the past eight years and served as a director for 13 years.
Dr Mazzo said Dr Snowdy oversaw the company's initial public offering on the ASX and took the about $10 million in revenue for 2021, a 38 percent growth over the prior year and recognition as a leader in paediatric myopia management.
"We thank Dr Snowdy for his service and wish him well in his new endeavor," said Dr Mazzo.
The company said it would begin a search for a replacement chief executive officer.
Visioneering fell 2.5 cents or 2.9 percent to 85 cents.

COCHLEAR

Cochlear says Tony Manna will retire as head of its North America operations with Lisa Aubert appointed as his replacement effective April 1, 2022.
Cochlear said Ms Aubert joined the company in 1994 and was currently the head of sales for North America and chair of the company's sales council.
Ms Aubert's Linkedin page said she held a Bachelor of Arts from Michigan State University, a Master of Art from the Detroit, Michigan'-based Wayne State University and a Master of Business Administration from England's Henley Business School.
Cochlear was up $4.39 or two percent to $219.11 with 164,125 shares traded.

RESAPP HEALTH

Resapp says it has appointed Prof Elizabeth Talbot, Prof Catherine Bennet, Prof Mark Howard and Prof Paul Porter to its Covid-19 scientific advisory board.

Resapp said the board would provide scientific and clinical advice to the company's Covid-19 programs which were focused on delivering Covid-19 screening and disease management tools.

The company said Prof Talbot was a Professor of Medicine in the infectious diseases and international health section at Hanover, New Hampshire's Dartmouth University and previously worked at the Centers for Disease Control and Prevention (CDC) and engaged in clinician education in West Africa during the 2014 Ebola outbreak.

Resapp said Prof Bennet was the head of Melbourne's Deakin University epidemiology.

The company said Prof Howard was the director of the Victorian Respiratory Support Service and Institute for Breathing and Sleep at Austin Health.

Resapp said Prof Paul Porter was a Resapp scientific advisor and had been the principal investigator on several of its clinical trials and was a consultant paediatrician and a director of Helsinki's Valo Therapeutics.

Resapp was unchanged at 5.7 cents with 1.4 million shares traded.