Biotech Daily

Monday January 17, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: AVITA UP 5.5%; USCOM DOWN 5%**

*** BDI-40, CANNABIS CORNER CHANGES**

*** IMMURON RECEIVES $306k FEDERAL R&D TAX INCENTIVE**

*** RESAPP: CLINICIANS BACK RESAPPDX FOR COVID-19**

*** MEMPHASYS 1st COMMERCIAL FELIX SALE FOR HUMAN IVF**

*** CLINUVEL ENROLS AFAMELANOTIDE FOR STROKE STUDY**

*** INOVIQ: US PATENT FOR BARD1 CANCER ANTIBODY TESTS**

*** MIND MEDICINE TRIALS PSYCHEDELICS BRAIN ACTIVITY**

*** BOD: UK APPROVES MARIJUANA FOR 'LONG COVID' TRIAL**

*** DR KATHRYN MACFARLANE REPLACES MAYNE DIRECTOR NANCY DOLAN**

*** CRESO APPOINTS WILLIAM LAY, MICHELINE MACKAY, BRUCE LINTON**

MARKET REPORT

The Australian stock market was up 0.32 percent on Monday January 17, 2022, with the ASX200 up 23.4 points to 7,417.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and one was untraded.

Avita was the best, up 16 cents or 5.5 percent to $3.08, with 460,918 shares traded. Resonance rose 5.4 percent; Compumedics and Micro-X climbed more than three percent; Clinuvel, Nanosonics, Neuren, Prescient and Pro Medicus were up more than two percent; Cochlear, Dimerix, Imugene, Oncosil and Opthea improved more than one percent; with CSL, Cyclopharm, Paradigm and Starpharma up by less than one percent.

Uscom led the falls, down 0.5 cents or 4.8 percent to 10 cents, with 281,660 shares traded. Pharmaxis fell 4.55 percent; Genetic Signatures lost 3.45 percent; Amplia, Antisense, Atomo, Emvision, Impedimed and Telix shed two percent or more; Cynata, Kazia, Immutep, Medical Developments and Polynovo lost more than one percent; with Mesoblast, Next Science, Resmed and Volpara down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40), CANNABIS CORNER

We have taken the Summer Holiday period to review the 140 companies covered by Biotech Daily and to make a number of changes.

Several companies have been promoted into and demoted from the Biotech Daily Top 40 Index (BDI-40) in the largest overhaul since inception.

The groupings are in batches of 20 companies and the question we ask is: “Does a company in a lower list deserve to replace a company in a higher list?”

The criteria are (in order): interesting and good science; benefit to human health; board and management competence; and likelihood to succeed. Market capitalization is observed but is not a determinant. We don’t like to replace companies developing cancer drugs with ones developing artificial intelligence or software, but it can happen.

The easy decision was to reduce Cannabis Corner from 22 companies to 11. The decisions were based on announcements to the ASX over the past two years and many companies appear to be either simply growing or importing marijuana and not doing much in the way of innovation or medicine. Esense and Palla Pharma made our lives a little easier by delisting and appointing administrators, respectively.

All decisions are under constant review and should a company be able to argue its case for promotion (we don’t expect any to argue for demotion) we are open to the discussion.

Bod Australia, Cann Global, Ecofibre, Elixinol, Esense, Hygrovest (MMJ Phytotech), Inahlerx (Lifespot), Little Green Pharma, MGC, Palla Pharma and Stemcell United have been removed from Cannabis Corner. (Having announced a trial of marijuana for long Covid Bod has proven an exception to the rule and is reported in this edition.)

Supporting our decision-making, the collective market capitalization of Cannabis Corner fell 28.5 percent with the removal of 50 percent of the companies. This does not imply in any way that those companies may or may not be profitable or well run. It means we don’t believe they are involved sufficiently in innovative medical projects for human health.

The First Eleven is: Althea, Auscann, Botanix, Cann Group, Creso, Cronos, Emyria, Epsilon, Incannex, Medlab and Zelira.

The BDI-40 promotions and demotions have been much harder.

There is only one change to the BDI-20, with Kazia replacing Paradigm, but Mesoblast and Starpharma have taken a long time to commercialize their technologies and remain in the Top 20 on probation. Both have product in the market, and despite low revenues and high losses can only be replaced by a drug developer with phase III success and sales.

Alterity, LBT, Optiscan and Osprey are being replaced in the Second 20 by Alcidion, Atomo, Emvision and Micro-X; with recent listings, Argenica, Aroa, Artrya, BCal, Clarity, Lumos, Pacific Edge, Radiopharm and Trajan promoted into the Third 20.

David Langsam, Editor

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JANUARY 1, 2022

Company $Am	**Jan-21**	**Dec-21**	**Jan-22**
Cochlear	12,425	14,326	14,405
CSL	128,840	139,795	140,034
Resmed	39,622	52,860	52,309
BDI-20			
Avita	530	485	426
Clinuvel	1,103	1,422	1,412
Compumedics	89	60	66
Cyclopharm	201	169	153
Cynata	95	75	78
Ellex	51	47	47
Genetic Signatures	287	188	256
Immutep	269	406	419
Kazia	146	187	166
Medical Developments	464	343	356
Mesoblast	1,322	1,103	882
Nanosonics	2,417	1,647	1,934
Neuren	147	227	475
Opthea	648	420	479
Pharmaxis	37	52	66
Polynovo	2,565	966	1,002
Pro Medicus	3,560	6,522	6,569
Starpharma	635	441	525
Telix	1,060	1,881	2,164
Volpara	360	287	262
Second 20			
Actinogen	30	229	284
Alcidion	183	356	336
Amplia	26	27	32
Antisense	75	135	130
Atomo	172	127	123
Dimerix	47	79	79
Emvision	221	201	207
Impedimed	135	302	311
Imugene	474	3,139	2,306
Micro-X	128	138	117
Next Science	243	245	246
Oncosil	98	36	36
Orthocell	83	100	101
Paradigm	576	478	431
Patrys	43	74	76
Prescient	43	156	150
Proteomics	83	126	128
Resonance	107	48	65
Universal Biosensors	77	157	176
Uscom	25	16	23

IMMURON

Immuron says it has received $306,154 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Immuron said the rebate related to expenditure for the year to June 30, 2021.
Immuron fell half a cent or 4.2 percent to 11.5 cents with 1.5 million shares traded.

RESAPP HEALTH

Resapp says a study of its Resappdx at Queensland's Health Hub Doctors Morayfield supports the use of the device for differentiating respiratory disease including Covid-19.

The article, titled 'Implementation of a novel digital diagnostic tool to support the assessment of respiratory disease in a Covid-19 fever clinic' was published in the British Medical Journal (BMJ) Innovations and the full article is available at: https://innovations.bmj.com/content/early/2022/01/11/bmjinnov-2021-000673.

Resapp said that the authors concluded that the device "proved to be a safe, simple and effective tool in the specialist respiratory clinic environment and successfully detected a range of respiratory diseases, sped up clinical care delivery and helped lower potential Sars-Cov-2 transmission risks".

The article said that Resappdx time to final result averaged 32 seconds.

It said that in the assessment cohort of 186 participants, the device identified 92 patients with undifferentiated lower respiratory tract disease (LRTD), 52 with pneumonia, three with croup, 32 with asthma exacerbation, and 23 with chronic obstructive pulmonary disease (COPD) exacerbation.

Overall, 49 assessments produced no finding, the journal article said.

The article said that in the computed tomography (CT) cohort of 21 participants, the device correlated with the radiological findings in 12 of 12 patients with undifferentiated LRTD, eight of nine patients with COPD and one of patient with pneumonia.

"In the single non-correlated COPD patient, the device indicated the presence of possible COPD exacerbation; however, there was no prior diagnosis of COPD and no evidence of COPD was reported radiologically," the article said.

"Of note, the patient was found to have an approximate 25 pack year history of cigarette use," the article said.

"Also, of note was the correct identification of pneumonia by the device in a Sars-Cov-2 positive patient where pneumonia was subsequently reported on CT as an atypical pneumonia," the article said.

The journal article said that in the treatment cohort of 30 participants, "the device identified 25 patients with pneumonia of whom the using physicians reached a final diagnosis and commenced treatment for pneumonia in 17 patients".

For the remaining patients in the cohort, the device and using physicians were in full concordance and identified one patient with croup, three with asthma exacerbation and one with COPD exacerbation," the article said.

Resapp managing-director Dr Tony Keating said the company was "very pleased to see that Resappdx was able to provide significant insight for clinicians assessing respiratory patients during the challenging conditions experienced in the early stages of the Covid-19 pandemic".

"Of note was that Resappdx correctly identified pneumonia in a patient with Covid-19, noting the very small number of Covid-19 positive cases in Queensland at that time," Dr Keating said.

"The identification of pneumonia is an important clinical step in the management of patients with Covid-19, helping identify patients where the virus has reached the lungs and need urgent clinical care, and reducing the number of non-critical cases unnecessarily referred to healthcare facilities, preserving resources for those that need them most," Dr Keating said.

Resapp was up 0.2 cents or 3.4 percent to 6.1 cents.

MEMPHASYS

Memphasys says the Coimbatore, India-based Women's Centre has made the first commercial purchase of its Felix sperm separation system for in-vitro fertilization.
Memphasys executive chair Alison Coutts told Biotech Daily the value of the sale of the system for human in-vitro fertilization (IVF) was "commercial-in-confidence".
In the media release, the company said that the contract included one Felix console and an initial supply of single use cartridges.
Memphasys said the console would initially be used for overcoming sperm quality issues by "quickly and gently separating high quality sperm from a semen sample for use in human IVF procedures".
The company said that the cartridge processed the semen sample to select sperm with the least DNA damage.
Memphasys said that one cartridge was used for each semen sample processed, providing separated sperm ready for use in in-vitro fertilization procedures after six minutes' processing.
The company said that the Women's Centre was one of the participants in its key opinion leader study, which involved 13 in-vitro fertilization clinics in eight countries.
Ms Coutts said the first commercial sale was "very exciting".
"It is the first time the Felix system will be put to routine clinical use, to produce embryos for implantation and pregnancies," Ms Coutts said.
"Whilst it is a small cartridge volume order to begin with, the Felix revenue model is based on the subsequent recurring sales of the cartridges," Ms Coutts said.
Memphasys fell half a cent or 5.95 percent to 7.9 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has enrolled and dosed all six stroke patients in its phase II study of afamelanotide, or Scenesse, for arterial ischaemic stroke, with no adverse reactions.
Clinuvel head of clinical operations Dr Pilar Bilbao said "the safety profile reported to date gives us much comfort to continue the program".
Dr Bilbao said that the company expected results and analysis this year.
Clinuvel said that while arterial ischaemic stroke accounted for about 85 percent of the 15 million cases of stroke each year, in Europe, more than 85 percent of arterial ischaemic stroke cases presenting to hospital were not eligible for the current standard-of-care treatment of clot removal and clot dissolution.
Clinuvel was up 70 cents or 2.8 percent to $25.83 with 45,751 shares traded.

INOVIQ (FORMERLY BARD1 LIFESCIENCES)

Inoviq says the US Patent and Trademark Office has issued a patent relating to its breast and ovarian cancer antibody tests.
Inoviq said the patent, titled 'Kits for detecting breast or ovarian cancer in a body fluid sample and use thereof', would protect the technology until November 28, 2032.
The company said the patent was a continuation of a previously granted patent, with additional claims directed towards a method for detecting Bard1 auto-antibodies associated with breast or ovarian cancer in body fluids and related assays, kits and peptides.
Inoviq fell 1.5 cents or 1.2 percent to $1.195.

MIND MEDICINE AUSTRALIA

Mind Medicine Australia says it is part-funding a 200-participant clinical trial of psychedelic drugs on brain activity, measured by electro-encephalography (EEG).
Mind Medicine said that there would 100 participants in each of the two arms of the study receiving “a single medical dose” of 3,4 methylene-dioxy-meth-amphetamine (MDMA or ecstasy) and 100 receiving psilocybin.
Mind Medicine said the trial was sponsored by Sydney’s Monarch Mental Health, which was formerly TMS (transcranial magnetic stimulation) Clinics, and the principal investigators for the trial would be Monash University’s Prof Paul Fitzgerald and Dr Neil Bailey.
The company said that to be eligible to participate in the trial, participants would be required to complete training in the administration of psychedelic assisted therapy through the Mind Medicine Institute’s Certificate in Psychedelic-Assisted Therapies course.
Mind Medicine said the lead therapists for the trial would be psychologist Nigel Denning and the Mind Medicine Institute psychotherapist Dr Tra-ill Dowie.
The company said the primary aim was to determine changes in brain activity, with secondary aims the assessment of changes in mood, personality, beliefs and social engagement.
Prof Fitzgerald said that the results of the study would “inform us as to whether these substances have an effect on brain activity related to cognitive and emotional processes which continues after the medicine session and may also provide information that can help explain how these substances have their clinical effects”.
Mind Medicine said it expected the trial to start this year.
Mind Medicine Australia is a registered charity.

BOD AUSTRALIA

Bod says it has UK Medicines & Healthcare Products Regulatory Agency authorization for a 30-patient, open-label, six-month trial of cannabidiol for long-Covid.
Bod said it intended to dose patients daily with its five percent cannabidiol product Medicabilis in collaboration with Drug Science UK, but that final protocol design and ethics approval had not been received.
The company said that Drug Science UK was founded in 2010 by Prof David Nutt, Imperial College London’s deputy head of the Centre for Psychedelic Research and was formerly the chair of the UK Advisory Council on the Misuse of Drugs, until he published a paper comparing the risks associated with horse-riding (one serious event for every 350 exposures), compared to taking ecstasy (one serious event for every 10,000 exposures).
The company said that “long-Covid” referred to symptoms that developed at least eight weeks following an initial Covid-19 infection, which might include the continuation of symptoms from when an individual was first infected, or new symptoms where individuals feel they have improved and a month after being infected symptoms arise again.
Bod said there was a range of long-Covid symptoms, including shortness of breath, fatigue, chest discomfort, loss of concentration, chronic pain, anxiety and insomnia”.
“Many of these symptoms may be amenable to treatment with cannabis-based medicinal products, highlighting a significant opportunity for Bod,” the company said.
Bod said the trial would allow it “to pursue a large market opportunity [with] an estimated 1.3 million people in the UK … suffering long-Covid with one in 40 Covid-19 infections having symptoms lasting upwards of three months”.
The company said that the principal investigator would be Dr Elizabeth Iverson.
Bod was up half a cent or 2.3 percent to 22.5 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has appointed Dr Kathryn MacFarlane a director effective from February 1, 2022, and Nancy Dolan will retire as a director at the end of February.
Mayne said that Dr MacFarlane had more than 30 years' experience in the pharmaceutical industry, most recently as the founder of the Washington, DC-based consultancy Smartpharma LLC.
The company said that previously Dr MacFarlane was an executive with the New Jersey-based Agile Therapeutics, Dublin's Warner Chilcott, and the Detroit-based Parke-Davis.
Mayne said that Dr MacFarlane held a Bachelor of Science and Doctor of Pharmacy from Purdue University.
Mayne was unchanged at 28 cents with 2.2 million shares traded.

CRESO PHARMA

Creso says it has appointed William Lay as managing-director, Micheline MacKay as executive director and Bruce Linton as a non-executive director.
Creso said that Mr Lay was previously the company's head of strategy, origination and operations, and previously worked at the Montreal, Canada-based BMO Capital Markets, and later at the Smiths Falls, Canada-based Canopy Growth.
The company said that Ms MacKay was currently the corporate manager of Creso's Canadian subsidiary Mernova, and had more than 22 years' experience in regulatory environments.
Creso said that Mr Linton had been appointed director in addition to his role as a consultant for the company, and was the founder and chairman of Canopy Group.
Creso fell 0.4 cents or 4.4 percent to 8.6 cents with 5.1 million shares traded.