Biotech Daily

Monday March 21, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PROTEOMICS UP 12%; PARADIGM DOWN 10%**

*** FEDERAL $28.1m FOR GEONOMICS AUSTRALIA**

*** UNIVERSITY OF NEW SOUTH WALES OPENS RNA INSTITUTE**

*** BAYMATOB RAISES $4.2m FOR OLI LABOR MONITOR**

*** ORTHOCELL: TGA APPROVES CELGRO REMPLIR FOR NERVE REPAIR**

*** LIVING CELL: SHORTFALL RAISES NO FUNDS; TOTAL $3.86m**

*** ANTEO TELLS ASX QUERY: 'WEBINAR HAD NO NEW INFORMATION'**

*** ASX SUSPENDS CHIMERIC OPTIONS**

*** RESAPP TAKES 'COVID RESULTS' HALT TO SUSPENSION**

*** VGI: STUDY BACKS DELTA-TOCOTRIENOL PHARMACO-KINETICS**

*** IMMUTEP WINS JAPAN LAG525 FOR CANCER PATENT**

*** CRESO: MARKET SHARE 'MILESTONE'; PLANT YIELD UP**

MARKET REPORT

The Australian stock market fell 0.22 percent on Monday March 21, 2022, with the ASX200 down 15.9 points to 7,278.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 21 fell, five traded unchanged and one was untraded.

Proteomics was the best, up 13 cents or 12.2 percent to $1.195, with 147,378 shares traded. Orthocell climbed 11.5 percent; Immutep improved 7.6 percent; Opthea was up 5.3 percent; Patrys improved 4.2 percent; Actinogen and Resonance rose more than three percent; Cynata, Dimerix and Volpara climbed more than two percent; Emvision, Nanosonics and Polynovo were up one percent or more; with Cochlear up by 0.4 percent.

Paradigm led the falls, down 12.5 cents or 9.96 percent to $1.13, with 545,421 shares traded. Compumedics and Starpharma lost more than six percent; Alcidion was down 5.3 percent; Atomo and Clinuvel fell four percent or more; Imugene, Mesoblast and Telix were down more than three percent; Genetic Signatures, Medical Developments, Next Science, Oncosil and Prescient shed more than two percent; CSL, Neuren, Pharmaxis and Universal Biosensors were down more than one percent; with Avita, Cyclopharm, Kazia, Pro Medicus and Resmed down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it will grant $28.1 million to establish Geonomics Australia "to support the integration of genomic medicine as a standard of healthcare".
A media release from Federal Health Minister Greg Hunt said genomic technologies had "the potential to reshape clinical practice and change the way we prevent, diagnose, treat and monitor illness throughout each person's life".
The media release said that Genomics Australia would be chaired by Prof Kathryn North and would attempt "to ensure that Australia was a world leader in the research, development and use of genomic medicine to save lives and protect lives".
The Federal Government said that Genomics Australia would become a Commonwealth entity under the Health portfolio from January 1, 2024 to advise the Government on the operation of the $500 million, 10-year "genomics mission".
The Government said that Genomics Australia would provide the coordination and strategic approach required to harness the discipline and accelerate the translation of genomic technologies into clinical practice and public health services.
"This will enable all Australians to access genomic testing and related healthcare services when necessary, providing faster and more accurate diagnoses and the identification of more precise and tailored treatments that can substantially improve health outcomes and save lives," the media release said.
In February, the Federal Government said it had allocated more than $150 million to 40 research projects as part of the $500 million Genomics Health Futures Mission, as well as $50 million for Omico to develop genomic testing (BD: Feb 4, 2022).

UNIVERSITY OF NEW SOUTH WALES

The University of New South Wales says it has formally opened that RNA Institute, to be a leading RNA science, therapeutics and translational facility.
A media release from the University said that it established the RNA Institute with a $25 million grant as part of a New South Wales RNA Bioscience Alliance between New South Wales universities and the New South Wales Government.
The University said that the Institute, eld by director Prof Pall Thordarson would build the State's capability to research, develop and manufacture RNA-based therapeutics.
The New South Wales Minister for Enterprise, Investment and Trade Stuart Ayres said that the launch was "a significant milestone in the creation of the significant RNA ecosystem we are establishing".
"A thriving [New South Wales]-based RNA industry underpinned by world-leading research talent will attract international investment and bring companies from all over the world to create high priority jobs … within the $2 billion medical technology growth industry," Mr Ayres said.
University of New South Wales vice-chancellor Prof Attila Brungs said the Institute would draw together the University's existing expertise to provide a foundation for increased collaboration and critical advances in RNA.
"[The University of New South Wales] is home to some of the best scientific minds in the world in this field," Prof Brungs said.
"In creating this Institute, we have brought together scientists, engineers, and medical researchers to work on key bottlenecks at the frontier of RNA science and medicine," Prof Brungs said.
The media release said the Institute would conduct pre-clinical trials for the treatment of Covid-19 and cancer using RNA-based therapeutics manufactured in New South Wales with pilot-scale production of small interfering RNA (siRNA) by June this year.

BAYMATOB PTY LTD

Baymatob says it has raised $4,215,000 for clinical trials of its Oli artificial intelligence labor monitoring device to predict post-partum haemorrhage.

The Sydney-based Baymatob said that the placement was cornerstoned by Australian Unity's Future of Healthcare Fund, with support from institutional and high net-worth investors.

The company said that the Oli wearable device used artificial intelligence to identify mothers during labor who were at high risk of developing post-partum haemorrhage well before giving birth.

Last year, Baymatob said it had US Food and Drug Administration breakthrough device designation for its Oli monitor (BD: Aug 17, 2021).

Today, Baymatob said that post-partum haemorrhage, or heavy bleeding after childbirth was a "serious complication of pregnancy and … the world's leading cause of preventable maternal death".

Baymatob chief executive officer Tara Croft said the investor support would enable completion of the 500-patient pilot study for a later Australian and US pivotal study.

Australian Unity's Future of Healthcare Fund manager Victor Windeyer said the fund was "proud to support the clinical development of Oli, which has the potential to improve outcomes and positively impact millions of women's lives globally".

"Baymatob's Oli is revolutionizing how mothers are monitored in labor, with an innovation that overcomes challenges that mothers, families and clinicians have had to accept for too long," Mr Windeyer said.

Baymatob is a private company.

ORTHOCELL

Orthocell says that the Australia Therapeutic Goods Administration (TGA) has approved its Celgro-based Remplir for use in peripheral nerve repair procedures.

Orthocell said that the approval validated its Celgro collagen device for suture-less repair, and was the second Celgro platform product to be approved, following last year's approval of Striate+ (BD: Jan 17, Mar 3, 2021).

Today, the company said it had planned to file an Australian reimbursement application by July 2022 which would define the minimum benefit value private insurers would pay for Remplir.

Orthocell said that Australia was a "significant" market with 11,780 surgical repairs of peripheral nerves in public and private hospitals in 2019-'20.

Orthocell managing-director Paul Anderson said that "Remplir is the first of its kind biological scaffold designed by an Australian team of researchers to mimic the outer layers of the peripheral nerve and facilitate high quality nerve repair".

"Remplir is the only Australian-manufactured medical device for nerve repair to gain Australian regulatory approval and is a significant inflection point for our company," Mr Anderson said.

Orthocell chief scientific officer Prof Minghao Zheng said that Remplir was "a paradigm shift in product design and application".

"It provides a barrier structure to protect the nerve and generates an ideal micro-environment for the regeneration of damaged peripheral nerves," Prof Zheng said.

"Remplir reduces the need for suturing, is easy to use and results in consistent and predictable return of muscle functions to paralyzed limbs … [and] will empower surgeons to improve the lives of patients with complex nerve injuries," Prof Zheng said.

Orthocell was up 4.5 cents or 11.5 percent to 43.5 cents with 7.1 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says that “no further funds have been raised” from the shortfall from its two-for-three rights issue at 0.8 cents a share.
In October 2021, Living Cell said it had raised $3.5 million in a placement and hoped to raise a further $4 million in a rights issue for a third trial of NTCell for Parkinson’s disease (BD: Oct 19, 2021)
In December, the company said its rights issued raised $361,264 with $250,000 in expenses and 180 Markets Pty Ltd would attempt to place the $3,445,942 “on a best endeavors basis” (BD: Jan 16, 2022).
Today, Living Cell said that due to “adverse market conditions, including [the] current conflict in Europe and the continued impacts of Covid-19, no further funds have been raised under the offer”.
The company said that it had “sufficient funding to advance its key NTCell project” for Parkinson’s disease, with cash $3.7 million as at February 28, 2022.
Living Cell was untraded at 0.6 cents.

ANTEOTECH

Anteo has told the ASX that there was no new information in its ‘Investor Update Webinar’ and therefore it did not view it as “price sensitive”.
On March 11, Anteo told the ASX that an update presentation on previously announced activities which it did not consider price sensitive, might have explained a recent share price fall (BD: Mar 11, 2022).
At that time, the ASX noted in its query that the company’s share price fell 7.3 cents or 42.9 percent from an open of 17 cents to a low of 9.7 cents on March 10, 2022 and observed a “significant increase” in the trading volume.
Today, Anteo said that in previous announcements it had made clear that manufacturing was “not a straightforward process, as issues arise from time to time” and that the “ordinary course of in-vitro diagnostic (IVD) scale-up manufacture does not follow a linear path, involves some unpredictability, involves challenges including quality optimization and quality control and, inevitably requires refinement”.
The company said the webinar comments were “merely intended to provide an update on the most recent issues that had been experienced and … [it] was now close to resolving”.
Anteo said that in a previous quarterly update it “made it clear that IVD supply is heavily regulated and that in order to operate successfully organizations must ensure the consistent manufacture of product of the highest quality and performance”.
Anteo fell half a cent or 5.05 percent to 9.4 cents with 79.1 million shares traded.

CHIMERIC THERAPEUTICS

The ASX says it has suspended Chimeric CHMO options “as deferred settlement trading will not be made available for them”.
The ASX said that the options were expected to be quoted on a normal settlement basis on March 28, 2022 and the suspension only applied to options and no other securities.
Chimeric chief financial officer Phillip Hains told Biotech Daily that the suspension of the options related to the timing of the recent issue of options to placement investors ahead of options to be issued under the rights issue to retail investors.
“The new options issued under both the institutional and retail entitlement offers are due to be allotted on March 25, to commence trading on March 28, 2022,” Mr Hains said.
Chimeric shares fell half a cent or 3.3 percent to 14.5 cents.

RESAPP HEALTH

Resapp has requested a suspension to follow its March 17 trading halt “pending the release of an announcement regarding its Covid-19 study results” (BD: Mar 17, 2022).
Last week, Resapp requested a trading halt “pending the release of an announcement regarding its Covid-19 study results” and said trading would resume on March 21, 2022 or on an earlier announcement (BD: Mar 17, 2022).
Today, the company requested that the voluntary suspension would end when the announcement was released to the market, expected to be tomorrow, March 22, 2022.
Resapp last traded at 6.2 cents.

VGI HEALTH TECHNOLOGY (FORMERLY AZURE HEALTH, INVICTUS)

VGI says that it has data supporting the pharmaco-kinetics of its delta-tocotrienol powder.
VGI said that an abstract will be presented to the American Society for Nutrition conference June 14 to 16, 2022, titled ‘Transmucosal delivery of tocotrienols from a delta-tocotrienol powder: A Multidose Pharmacokinetic study’.
The company said that scientific adviser Dr Jordan Moon conducted the pharmaco-kinetics study using new formulations developed for the transmucosal delivery of tocotrienols (BD: Dec 7, 2021).
VGI said that the data supported the greater flexibility with doses for the drug delivery platform than earlier research data had suggested.
The company said that 16 healthy research subjects were randomly administered either 40mg or 80mg of a delta tocotrienol (DT3) containing powder in a fasted state, with blood samples taken at 0, 60, 90, 120, 180, 240, 360, and 480 minutes.
VGI said that subjects were given a meal consisting of carbohydrates, proteins and fats after four hours and DT3 concentrations were calculated from blood plasma using protein precipitation followed by liquid-liquid extraction.
The company said that DT3 bio-availability was assessed using the parameters: peak plasma concentration (Cmax), time to reach peak plasma concentration (Tmax) and total area under the plasma concentration-time curve (AUC).
VGI said that Cmax for the 40mg group was 44.05 nanogram/millilitre (ng/ml) and 127.4ng/ml for the 80mg group.
The company said that Tmax was achieved at 360 minutes for both the 40mg and 80mg group and area under the curve for the 40mg was 9,941.6 ng/ml minutes, with a 2.9-times increase for the 80mg group of 29,072.2 ng/ml minutes.
VGI said that the transmucosal delivery of tocotrienols from a delta-tocotrienol powder containing 40mg and 80mg of DT3 “resulted in a progressively elevated absorption rate for both doses with 80mg appearing to increase total plasma DT3 by a difference of 2.9 times that of a 40mg dose”.
The company said that both doses showed enhanced plasma DT3 concentrations in healthy men and women over a period of no less than eight hours.
Dr Moon said the delivery platform could “accommodate a wide range of doses and there appears to be a clear linear and predictable dose response”.
“This creates a novel opportunity … to develop new products to add to its pharmaceuticals and [food additives] product pipeline,” Dr Moon said.
VGI said the next study to be conducted by Dr Moon would be a multiple ascending dose pharmaco-kinetics study and one assessing physical exercise performance and recovery parameters.
On the National (formerly Newcastle) Stock Exchange VGI was untraded at 10 cents.

IMMUTEP

Immutep says that the Japanese Patent Office has granted a patent relating to its LAG525 for the treatment of cancer.

Immutep said the patent, titled 'Antibody molecules to LAG-3 and uses thereof' would protect its intellectual property until March 13, 2035.

The company said that the patent claims were directed to pharmaceutical compositions for use in the treatment of cancer, where the compositions comprised LAG525 in a specific dose and for use in a defined treatment regimen, as well as administered in combination with a second agent such as an anti-programmed death-1 (PD-1) antibody, and anti-PD0-ligand1 antibody or a chemotherapy agent.

Immutep said the patent was co-owned by Novartis AG and its wholly-owned European subsidiary Immutep SAS.

Immutep was up three cents or 7.6 percent to 42.5 cents with 4.4 million shares traded.

CRESO PHARMA

Creso says that Canada subsidiary Mernova Medicinal reached a "major milestone, achieving a market share of [more than] five percent" in Nova Scotia.

Creso said that Mernova had progressed "several initiatives to further improve its growing process to increase plant yield and quality" including investments in higher quality nutrition products, irrigation system upgrades and lighting.

Creso was up 0.3 cents or 5.45 percent to 5.8 cents with five million shares traded.