Biotech Daily

Monday March 14, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MICRO-X UP 25%; CYNATA DOWN 6.5%**

*** VICTORIA, SOUTH KOREA mRNA VACCINE PARTNERSHIP**

*** BIONOMICS RECEIVES CANCER THERAPEUTICS CRC $264k**

*** ANTISENSE: 'ATL1102 IMPROVES BONE DENSITY'**

*** MEMPHASYS: DRAFT ISO 13485 FOR MANAGEMENT SYSTEMS**

*** EBR: LEADLESS PACEMAKER INCLUDED IN SOLVE-CRT TRIAL**

*** OSTEOPORE, SINGULAR STUDY AI DESIGN FOR CRANIAL IMPLANTS**

*** ALLEGRA: 'SYSTEMIC SAFETY FOR SR-HT-GAHNITE DEVICE'**

*** ZELIRA 175-TO-1 CONSOLIDATION EGM**

*** PERENNIAL TAKES 12.6% OF LUMOS**

*** STARFISH II TRANSFERS DORSAVI SHARES TO NOMINEES**

*** ANTEOTECH: CHAIR JACK HAMILTON TO GO; CHRIS PARKER EXECUTIVE**

MARKET REPORT

The Australian stock market was up 1.21 percent on Monday March 14, 2022, with the ASX200 up 85.8 points to 7,149.4 points. Eighteen of the Biotech Daily Top 40 stocks were up, 15 fell and seven traded unchanged. All three Big Caps were up.

Micro-X was the best, up four cents or 25 percent to 20 cents, with 440,520 shares traded. Antisense climbed eight percent; Proteomics rose 6.4 percent; Alcidion, Mesoblast and Uscom were up more than five percent; Amplia, Polynovo and Resonance improved more than three percent; Cochlear, CSL, Nanosonics, Neuren and Pro Medicus rose two percent or more; Avita, Emvision and Universal Biosensors were up more than one percent; with Clinuvel, Paradigm, Resmed and Starpharma up by less than one percent.

Cynata led the falls, down three cents or 6.45 percent to 43.5 cents, with 124,698 shares traded. Medical Developments lost five percent; both Atomo and Immutep fell four percent; Compumedics and Orthocell were down more than three percent; Actinogen, Cyclopharm and Dimerix shed more than two percent; Genetic Signatures, Opthea, Pharmaxis and Volpara were down more than one percent; with Kazia and Telix down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says it has a new memorandum of understanding with South Korea on mRNA research and development, clinical trials and manufacturing.

A media release from the Victoria Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said the agrrement was between mRNA Victoria and the Osong-based Korean Health, Industry Development Institute (KHIDI) and would “will bring together Victoria’s biotech research expertise with Korea’s bio-manufacturing specialization, to boost the development of the RNA ecosystems of both jurisdictions”.

The State Government said that Victoria and South Korea had “committed to exchange information and facilitate linkages between industry, research and government organizations on opportunities for joint early-stage RNA research, clinical trials and investment into the development and manufacture of new RNA-based therapies and vaccines”.

The Victoria Government said that the agreement “envisages government-to-government collaboration on policy approaches for fostering innovation and supporting local industry development, including direct cooperation on capability building initiatives in Victoria and [South] Korea”.

The media release said the Korean Health, Industry Development Institute was overseen by the Ministry of Health and Welfare “to strengthen [South] Korea’s national health industry and drive [South] Korea’s innovation agenda on pharmaceuticals, medical devices and medical services” and supports a pledge to invest $2.4 billion for South Korea to become one of the world's five largest Covid-19 vaccine manufacturing bases by 2025, with a commitment to establish a bio-manufacturing training hub in Seoul for workforces from around the world, in a partnership with the World Health Organisation.

The State Government said that through mRNA Victoria, it was “delivering on this commitment by supporting pre and clinical medical research, commercialization, clinical trials, supply chain development, clinical and commercial manufacturing”.

The Victoria Government said the agreement “signals a positive partnership that benefits Victoria’s growing RNA ecosystem and was facilitated with the assistance and support of [the Department of Foreign Affairs and Trade] and Austrade”.

Ms Pulford said that Victoria had “Australia’s largest biomedical ecosystem and is leading Australia’s RNA technology research and manufacturing development”.

“This [memorandum of understanding] provides an exciting opportunity to combine Victoria’s biotech research expertise with [South] Korea’s biomanufacturing knowhow, to boost the development of our respective RNA ecosystems and cooperation on regional pandemic preparedness,” Ms Pulford said.

South Korean Health, Industry Development Institute executive director Dr Young-ok Kim said the agreement “will bring more collaborations in the RNA-based technology field between two organizations for securing new healthcare technologies and contribute to the development of global RNA ecosystem and future pandemic response together”.

BIONOMICS

Bionomics says it has received $263,634 in licencing revenue from its participation in the Cancer Therapeutics Cooperative Research Centre.

Bionomics said that the Cooperative Research Centre, also known as CTX had licenced two targets to Pfizer under a potential $US460 million ($A633.3 million) deal.

In 2018, Bionomics said it had earned $654,000 in licencing revenue from CTX under the Pfizer agreement (BD: Dec 21, 2018).

Bionomics fell 0.3 cents or 4.3 percent to 6.7 cents with 3.5 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says plasma protein data from its phase II trial of ATL1102 for Duchenne muscular dystrophy supports the potential of ATL1102 for improving bone density.
Antisense said the data was presented at the Muscular Dystrophy Association Clinical & Scientific Conference in a poster titled 'ATL1102 treatment in non-ambulant boys with DMD modulates plasma proteins with roles in [transforming growth factor]-beta mediated fibrosis, and cartilage and bone physiology'.
In 2020, the company said its nine-patient ATL1102 Duchenne muscular dystrophy (DMD) trial met its safety primary endpoint and indicated some efficacy (BD: May 22, 2020).
Today, Antisense said that as part of the phase II study, a large-scale protein analysis, of retained blood plasma samples was undertaken to identify proteins affected to provide further insight into the mode of action and biological activity of ATL1102.
The company said that statistically significant mean increases in bone morphogenetic protein-5 (BMP-5) (46.2%) and BMP-6 (34.4%) were observed at 24 weeks compared to baseline levels ($p < 0.0005$).
Antisense said that compared to an external healthy adult proteomics dataset used as a control, the baseline BMP-5 and BMP-6 levels of patients in the phase II study were below average with the levels of each protein increasing to near the external healthy adult control mean by the end of the 24-week ATL1102 dosing period.
The company said BMP-5 and BMP-6, were part of the transforming growth factor-beta (TGF-beta) family of proteins and both played a role in cartilage and bone formation.
Antisense said ATL1102's effect in increasing blood levels of BMP-5 and BMP-6 to healthy controls "suggests the potential for ATL1102 to improve bone density in DMD".
The company said that higher serum BMP-6 levels were associated with improved elbow flexion in patients with Duchenne muscular dystrophy, which appeared to correlate with the positive effects seen on elbow function in the trial.
Antisense said that BMP-5 and BMP-6 levels were reduced with cortico-steroid use and the prior administration of cortico-steroid appeared to have reduced baseline levels to below normal in the non-ambulant boys in the phase II trial.
The company said that DMD patients had an increased risk of bone fractures due to bone fragility through progressive muscle weakness affecting bone strength and prolonged cortico-steroid use reduced bone density and increased the risk of bone fractures.
Antisense said the data "adds further compelling evidence of ATL1102's unique and highly relevant mechanism of action in its application as a potential DMD treatment".
Antisense was up one cent or eight percent to 13.5 cents.

MEMPHASYS

Memphasys says it has draft International Organization for Standardization 13485 certification for its sperm separator quality management system.
Memphasys said its accreditation regulatory body the British Standards Institute performed the audit, with final certification in process.
The company said the ISO certification assisted its ability to sell medical devices, including its Felix and other sperm separation devices, in "high regulatory markets" such as Australia, Europe and China, and was "an important accreditation … in other markets".
Memphasys chair Alison Coutts said that she was "pleased that Memphasys has received this initial certification and that final certification is being processed".
Memphasys said that it used the specialist software system Greenlight Guru to implement its quality management system.
Memphasys was unchanged at 6.2 cents with 1.2 million shares traded.

EBR SYSTEMS

EBR says the US Food and Drug Administration has agreed to include wireless pacemakers as a co-implant in its pivotal Solve-CRT clinical trial.

EBR said that the Solve cardiac re-synchronization therapy (Solve-CRT) trial was originally designed to include patients with conventional pacemakers but this update expanded “the patient pool for the Solve-CRT trial to include patients with a leadless right ventricle pacemaker, that can be paired with the Wise System to deliver CRT”.

The company said that the Wise system was a wireless, endo-cardial pacing system in use for stimulating the heart’s left ventricle, the ventricle that is “thought to be a potentially superior, more anatomically correct pacing location”.

“While future labelling is subject to multiple factors including regulatory approvals, the inclusion of leadless pacemakers in the Solve-CRT trial indicates the FDA will consider whether to approve the Wise CRT System for use with wireless pacemakers as on-label treatment at the time of pre-market approval application,” the company said.

EBR chief executive officer John McCutcheon said the development had “the potential to meet a significant unmet clinical need by providing a solution to physicians whose patients with leadless pacemakers have no other upgrade options”.

“Leadless pacemakers represent a fast-growing market in cardiac rhythm management and this update makes Wise the only device that can potentially support the upgrade of patients currently implanted with a leadless right ventricle pacemaker,” Mr McCutcheon said.

Mr McCutcheon said the trial was on-track to complete recruitment as scheduled and EBR looked forward to “initiating our totally leadless CRT study in Australia and Europe, which builds on our dataset of patients treated with Wise and leadless pacemakers”.

EBR was up 3.75 cents or 5.8 percent to 68.75 cents.

OSTEOPORE

Osteopore says it has begun a study with Singular Health Group to improve the accuracy and efficiency of its customized cranial implants.

Osteopore said that Perth’s Singular Health, with the Commonwealth Scientific and Industrial Research Organisation’s Data61, had 91 percent accuracy for designing a cranial implant in less than four minutes using its artificial intelligence (AI) design engine.

The company said its customized implants were developed through computed tomography (CT) scans of patients provided by surgeons, which were processed by software converting them into three-dimensional models, which can then be used to print three-dimensional implants.

Osteopore said the objective of Singular Health’s artificial intelligence design engine was “to reduce modelling time, while maintaining or improving design accuracy”.

The company said it would begin a comparative study with Singular Health which would build on these results and “collate empirical data to develop a pathway to full [US Food and Drug Administration] approval for [an] AI model and deployment in Osteopore cranial applications”.

Osteopore said that the study would validate the accuracy and efficiency of the AI-model and its “3Dicom surgical software” where manual edits may be conducted to increase the implant accuracy to 100 percent, against its existing workflow.

The company said that expected outcomes from the study would include a “reduction in product-to-customer timeframes and improved implant quality”.

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

ALLEGRA ORTHOPAEDICS

Allegra says it has met a milestone after an article was published showing the “systemic safety” of its Sr-Ht-Gahnite material.

Allegra said that the study, titled ‘Design and evaluation of 3D-printed Sr-Ht-Gahnite bioceramic for FDA regulatory submission: A Good Laboratory Practice sheep study’, was authored by its engineer Ellen Newsom and the University of Sydney’s Prof Hala Zreiqat and was published in Acta Biomaterialia, and an abstract was available at: https://www.sciencedirect.com/science/article/abs/pii/S1742706122000459?via%3Dihub.

The company said that the study showed systemic safety of its Sr-Ht-Gahnite cervical fusion cage following the implantation of the spinal cage in sheep.

The company previously said Sr-HT–gahnite was composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite, a zinc-aluminium-oxide (BD: Jun 8, 2016).

In January, Allegra said that all animals in its sheep study had the Sr-Ht-Gahnite spinal cage device “implanted successfully” (BD: Jan 31, 2022).

Today, Allegra said that there were “no major changes in blood haematology or biochemistry parameters observed, no system distribution of strontium to the blood and wool, and no macroscopic or histopathological abnormalities in the distant organs when Sr-Ht-Gahnite was implanted, compared to baseline and control values”.

The company said the study addressed questions from the US Food and Drug Administration regarding the presence of strontium and that it was “on track to obtain a 90-day FDA 510(k) clearance for the US in the next 12 months”.

“The study has been performed under good laboratory practice, in line with FDA requirements for assessment of a new interbody fusion device, making the results broadly applicable to the translation of sheep models to the human cervical spine; and also the translation of Sr-HT-Gahnite as a biomaterial for use in additional applications,” the journal article said.

“Its findings are directly applicable to researchers and clinicians working in bone repair and the development of synthetic biomaterials,” the study said.

Allegra was unchanged at 17 cents.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says that it will hold an extraordinary general meeting to vote on a 175-to-one stock consolidation.

According to its most recent filing, Zelira had 1,675,101,964 shares on issue, implying that after the consolidation it would have about 9,572,011 shares on issue.

Biotech Daily calculates that at its current share price of 1.8 cents a share, it would trade at about $3.15 a share after the consolidation.

The virtual meeting will be held on April 12, 2022 at 9am (AWST).

Zelira was up 0.1 cents or 5.6 percent to 1.9 cents with 1.9 million shares traded.

LUMOS DIAGNOSTICS

Perennial Value Management says it has increased its substantial holding in Lumos from 17,328,013 shares (11.52%) to 19,060,257 shares (12.64%).

Perennial said that between February 28 to March 10, 2022, it bought and sold shares on market, with the single largest purchase 2,702,215 shares for $1,319,762 or 48.8 cents a share.

Lumos was up 3.5 cents or 9.2 percent to 41.5 cents.

DORSAVI

Starfish Technology Fund II LP says it has ceased its 60,597,345-share substantial holding in Dorsavi, after the “disposition of legal title to ordinary shares”.

Starfish Technology Fund II LP said it had disposed of the shares to Starfish Technology Fund II Nominees A Pty Ltd as trustee for the Starfish Technology Fund II Trust A and to Starfish Technology Fund II Nominees B Pty Ltd as trustees for Starfish Technology Fund II Trust B.

At the same time Starfish Technology Fund II Trust B, with HV Lodge LLC and Mantra Secondary Opportunities II SCA-SIF said they had increased their substantial holdings in Dorsavi from 18,646,557 shares (5.22%) to 48,763,229 shares (13.78%).

Starfish Technology Fund II Trust A and Perpetual Trustee as trustee for Stafford Private Equity 4 Fund said they had increased their substantial holdings in Dorsavi from 18,464,557 shares (5.22%) to 48,763,230 shares (13.78%).

Dorsavi was untraded at 2.2 cents.

ANTEOTECH

Anteotech says it is looking for a successor to the current chair, Dr Jack Hamilton and has promoted non-executive director Christopher Parker to executive director.

Anteotech said Dr Hamilton announced his intention to retire and the company requested he remain until a successor was identified.

The company said that Mr Parker was previously its chief executive officer between April 2018 and May 2019 and was an executive director until November 2019 when he was appointed a non-executive director.

Anteotech said that Mr Parker previously was Roche Diagnostics UK and Ireland managing-director and held other roles in general management, marketing and business development in Canada, Asia and Australia.

Anteotech was up 1.1 cents or 11.7 percent to 10.5 cents with 69.3 million shares traded.