Biotech Daily

Tuesday June 21, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: RESONANCE UP 18.5%; USCOM DOWN 9%**

*** RESAPP FAILS CONFIRMATION TARGET, PFIZER TO PAY $127m**

*** SDI FREIGHT COSTS 16-22% PROFIT WARNING**

*** MACH7 $3m CABELL HUNTINGTON CONTRACT RENEWAL**

*** WEHI 'REDUCES CAR-T-CELL TOXICITY'**

*** ANTERIS: DURAVR 6-MONTH FOLLOW-UP 'MARKED IMPROVEMENT'**

*** VOLPARA, MICROSOFT 'CARDIO-VASCULAR ISSUES' TEST**

*** PROTEOMICS LICENCES QIMR OESOPHAGEAL CANCER BIOMARKERS**

*** RECCE: 4,000mg R327 'SAFE, WELL-TOLERATED'**

*** RACE DATA BACKS ZANTRENE FOR FTO CANCERS**

*** RADIOPHARM APPOINTS PROF SUSANN BRADY-KALNAY ADVISER**

MARKET REPORT

The Australian stock market was up 1.41 percent on Tuesday June 21, 2022, with the ASX200 up 90.4 points to 6,523.8 points. Twenty of the Biotech Daily Top 40 stocks were up, 17 fell and three traded unchanged.

Resonance was the best on no news, up one cent or 18.5 percent to 6.4 cents, with 186,437 shares traded. Antisense climbed 8.2 percent; Compumedics, Imugene and Opthea improved more than six percent; Clinuvel, Nova Eye and Proteomics were up five percent or more; Immutep and Micro-X were up more than four percent; Emvision was up 3.5 percent; Nanosonics rose 2.65 percent; Avita, Next Science, Pro Medicus, Telix and Universal Biosensors were up more than one percent; with Genetic Signatures, Kazia, Neuren and Resmed up by less than one percent.

Uscom led the falls, down 0.6 cents or 8.7 percent to 6.3 cents, with 140,980 shares traded. Actinogen and Volpara lost six percent or more; Amplia shed 5.3 percent; Oncosil, Paradigm, Patrys and Pharmaxis fell more than four percent; Cyclopharm and Orthocell were down more than three percent; Medical Developments, Mesoblast, Polynovo and Starpharma shed more than two percent; with Atomo, Cochlear, CSL, Cynata and Impedimed down by more than one percent.

RESAPP HEALTH

Resapp says its Covid-19 algorithm confirmation study performed “significantly lower than the … pilot study” meaning Pfizer will pay $127 million for the company.

Last week, Resapp said that Pfizer Australia agreed to increase the scheme consideration from 11.5 cents a share, valuing the company at about $100 million, to 20.7 cents a share on satisfaction of a confirmatory data readout condition, valuing it at about $178 million, or to 14.6 cents a share if the confirmatory data condition was not satisfied, valuing the company at about $125 million (BD: Jun 14, 2022).

Today, the company said that the confirmatory study achieved a sensitivity of 84 percent and a specificity of 58 percent significantly lower than the pilot study.

Resapp said the results were below the thresholds required to satisfy the Pfizer condition under the revised scheme, which consisted of a minimum sensitivity of 86 percent and a minimum specificity of 71 percent.

The company said that the results were calculated by Resapp and independently analyzed and verified by an independent third-party statistician.

In March. Resapp said its 741-paitent pilot trial shows that its cough diagnostic screening test could “correctly detect Covid-19 in 92 percent of people with the infection” with a sensitivity of 80 percent (BD: Mar 22, 2022)

The company said that as the confirmatory data readout condition under the revised scheme was not satisfied, the scheme consideration would be 14.6 cents a share in cash, representing an equity value of $127 million.

Resapp said the 14.6 cents price was a 62.2 percent premium to the close on April 8, the last trading day prior to announcement of the initial scheme and a 63.0 percent premium to the one-month 5-day volume-weighted average price to April 8, 2022.

The company said its board unanimously recommended that shareholders vote in favor of the scheme, in the absence of a superior proposal and subject to the independent expert concluding and continuing to conclude that the revised scheme was in the best interests of shareholders.

Resapp managing-director Dr Tony Keating said the company was “confident that our algorithms can detect Covid-19 using cough sounds, [but] they will require further refinement, testing and validation to ensure that they perform to the level needed”.

“This work will continue with the benefit of now having over 1,300 additional cough sound recordings with gold standard [polymerase chain reaction] test results to use to train and improve the algorithms,” Dr Keating said.

“Notwithstanding, the results underscore the considerable work, challenge and cost of bringing our technology to market,” Dr Keating said.

“Pfizer’s all cash offer represents an attractive 62 percent premium to our share price prior to announcement of the initial scheme and removes any risk associated with the future development and commercialization of Resapp’s technology,” Dr Keating said.

Resapp fell five cents or 28.6 percent to 12.5 cents with 38.2 million shares traded.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says it expects a 16 percent increase in sales for the 12-months to June 30, 2022 to $95.0 million but up to a 22 percent fall in after tax-profit to $7.0 million to $7.5 million.

SDI said sales of dental technology products were expected to increase 16 percent to about $95.0 million, compared to the prior corresponding period of $81.6 million, but that increased freight costs would impact its net profit after tax by 16 to 22 percent, to be in the range of $7.0 to $7.5 million, compared to the 12-months to June 30, 2021 of $8.9 million.

SDI was up three cents or 3.8 percent to 82.5 cents.

MACH7 TECHNOLOGIES

Mach7 says it has a $2.8 million, five-year contract renewal with Cabell Huntington Hospital in West Virginia.
Mach7 said the contracts were for Cabell's enterprise imaging platform and support for the Eunity diagnostic enterprise viewer.
The company said it had converted the existing capital term licence with Cabell to a five-year subscription agreement based on image volume.
Mach7 said that the total value of the contract renewal was $2.8 million, with a combined annual recurring revenue value of $562,732, recognized quarterly from July 2022.
Mach7 was up 1.5 cents or 3.1 percent to 50 cents.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute of Medical Research says it has developed a way to potentially reduce the toxic side-effects of Car-T-cell immunotherapy treatments.
The Institute said that chimeric antigen receptor T-Cell (Car-T-Cell) immunotherapy enhanced a patient's killer immune cells to attack and eliminate cancer but had harmful side-effects, with "about 50 percent of patients experiencing dangerous complications".
WEHI said it needed to redesign the T-Cells in order to generate different versions of chimeric antigen receptors to customize them to a patient's potency requirements.
WEHI said that a study, conducted with the Rehovot, Israel-based Weizmann Institute of Science, had "designed a way to identify a 'goldilocks' window that strikes a balance of safety and efficacy".
The Institute said that research article, titled 'De novo-designed transmembrane domains tune engineered receptor functions', was published in the journal Elife and was wavailable at: https://elifesciences.org/articles/75660.
WEHI said researchers hoped "their tool could be used to triage immunotherapy patients based on the level of potency they require in early phases of their treatment and bring the field closer to striking that 'goldilocks' treatment window for many different cancers".
The Institute's Prof Matthew Call said that previous studies attempted to fine-tune T cells by targeting the end sections of the sensor, which either bind to the cancer cell or instruct the T-cells to kill, the new research is the first to look at redesigning the middle part.
"Focusing on the connector fragment in the middle allows us to generate different versions of Cars that we know are stronger or weaker, enabling us to customise them to a patient's potency requirements," Prof Matthew Call said.
"Being able to predictably tune this T-cell activity significantly broadens our research, contrary to previous studies, because we are targeting something that exists in every immunotherapy scenario," Prof Matthew Call said.
"For the first time, we can establish rules that will be applicable to any cancer where Car-T-cell immunotherapy is being used," Prof Matthew Call said.
WEHI researcher Prof Melissa Call said that the ability to fine-tune T-Cells would "dramatically reduce the number of patients experiencing severe side-effects from the treatment, which can include fever, high blood pressure and respiratory distress".
"The therapy has incredible potential for cancer patients, but is currently used as a last resort due to these potentially severe side-effects," Prof Melissa Call said.
"Our tools could lead to a fundamental rethink of the way [Car-T-Cell] therapy is offered by reducing a patient's exposure risk to harmful side-effects…. this would allow patients with a broad range of cancers to be given [Car-T-Cell] therapy far earlier in the treatment process," Prof Melissa Call said.
The Institute said the next research phase would take the findings to the clinic.

ANTERIS TECHNOLOGIES

Anteris says an informal six-month follow-up of the first cohort in its Duravr trans-catheter heart valve study has shown “marked improvements” in all five patients.

Anteris said the six-minute walk test was “a key marker of patient well-being” and had improved 46 percent since baseline, and 21 percent between three and six months.

In January, the company said 30-day follow up results of five patients in its 10-patient, first-in-human study of Duravr trans-catheter heart valve met or exceeded their study objectives, with all five patients reporting no adverse events, no clotting and no heart rhythm disturbances due to the procedure (BD: Jan 24, 2022).

Today, Anteris chief medical officer Dr Chris Meduri said that “we are thrilled to see our patients doing so well six months after receiving Duravr… the valve is demonstrating clinically relevant haemo-dynamics, laminar flow and patient outcomes”.

Anteris was up $2.11 or 10.1 percent to $23.00.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it will work with Microsoft to research and develop software that uses mammograms to detect cardio-vascular issues.

Volpara said that with the Redmond, Washington-based Microsoft, it would develop a product that could detect and quantify breast arterial calcifications (BACs), which have been shown to be associated with cardio-vascular disease outcomes.

The company said the collaboration would use artificial intelligence to develop a tissue composition map that identified and quantified BACs from a mammogram.

Volpara did not disclose the commercial details of the collaboration but said Microsoft engineers and artificial intelligence specialists would assist with improving its BACs model and data processing, as well as the product’s technical development.

The company said that its US Food and Drug Administration-approved core algorithm. had been used to assess the breast composition of more than 14.5 million women through its analysis of more than 60 million mammography and tomosynthesis images. Volpara said the images were “one of the world’s largest de-identified image datasets” and would be a resource for the breast arterial calcifications project.

The company said that the breast arterial calcifications product, as a cardiac decision-support tool for radiologists, would mark its entrance into a new area of care, part of a $US146.4 billion cardiovascular disease market.

Volpara said that it had access to more than 35 percent of the US breast screening market and had the installation base to facilitate roll-out and adoption of the product, providing a new revenue stream.

The company said that, for women, the breast arterial calcifications product would add a new dimension to their regular breast screenings, providing information about their cardio-vascular health, with any significant findings delivered through the Volpara Breast Health Platform directly to the healthcare provider or through Volpara’s partner network.

Volpara chief science and innovation officer Dr Ralph Highnam said that “our mission and vision around the future of healthcare align well with Microsoft’s”.

“Though we are in the early stages of BAC product development, this collaboration will accelerate our efforts as we advance science together,” Dr Highnam said.

Microsoft New Zealand partner lead Matt Bostwick said that “with one in three deaths in New Zealand caused by cardio-vascular disease, this new research and development collaboration means that, together, we can detect and identify earlier symptoms of heart disease in women”.

Volpara fell three cents or 6.4 percent to 44 cents with 1.6 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has licenced biomarkers for oesophageal adenocarcinoma from the Queensland Institute for Medical Research Berghofer.

Proteomics said that the licence allowed it to use the biomarkers discovered by Brisbane's QIMR to develop and commercialize a simple blood test for oesophageal adenocarcinoma, the most common form of oesophageal cancer.

The company did not disclose the commercial terms of the agreement, but the licence was for 20 years or the life of the patents, and there were various milestones to complete the development and commercialization of licenced products, including royalty payments to QIMR for the sale or licence of the products, varying on a percentage basis based on the type of product developed and the sales proceeds received for those products.

In February, Proteomics said it had completed a 300-patient biomarker validation study for oesophageal adeno-carcinoma, with the Institute (BD: Feb 4, 2022).

Today, the company said it would undertake additional studies to confirm the diagnostic performance of the potential new blood test, which would take about six months.

Proteomics managing-director Dr Richard Lipscombe said that the test would be targeted at patients with Barrett's oesophagus, a pre-malignant condition associated with an increased risk of oesophageal cancer and that "these at-risk patients are currently screened with invasive and costly endoscopy procedures".

Dr Lipscombe said he hoped to use "a simple blood test" to detect oesophageal adenocarcinoma.

Proteomics was up 4.5 cents or 5.8 percent to 82.5 cents.

RECCE PHARMACEUTICALS

Recce says the sixth cohort 4,000mg dose of intravenous synthetic antibiotic candidate R327 in 10 healthy male subjects showed "good safety and tolerability".

Recce said the sixth cohort was an 80-fold increase on the 50mg dose of R327 in cohort one, and a review of the data would be conducted by an independent safety committee with the expected recommendation to commence recruitment for the seventh cohort.

Recce said the phase I, ascending dose, randomized, placebo-controlled, blinded study was evaluating the safety and pharmaco-kinetics of R327, at doses from 50mg to 16,000mg, and was expected to complete dosing by June 30, 2022.

Recce was up 9.5 cents or 16.8 percent to 66 cents.

RACE ONCOLOGY

Race says two abstracts on the anti-cancer uses of Zantrene, or bisantrene, support its use in targeting fat mass and obesity-associated protein (FTO).

Race said the abstracts were published in the journal Cancer Research, with the first, titled 'Targeting FTO suppresses pancreatic carcinogenesis via cancer stem cell maintenance', presented at the American Association of Cancer Research conference in New Orleans, from April 8 to 13, 2022.

The paper concluded that targeting fat mass and obesity-associated protein (FTO) might be "an attractive therapeutic approach for pancreatic cancer".

The company said the second poster, titled 'Novel evidence for FTO as an oncogenic player and mediator of chemoresistance in colorectal cancer' showed the potential use of an FTO inhibitor as an adjunctive treatment to fluorouracil-based chemotherapy for colorectal cancer patients.

Race was up 15 cents or 9.9 percent to $1.665.

RADIOPHARM THERANOSTICS

Radiopharm says it has appointed Prof Susann Brady-Kalnay to its scientific advisory board.

Radiopharm said that Prof Brady-Kalnay was a professor at the Cleveland, Ohio-based Case Western Reserve University's department of molecular biology and microbiology and founded the diagnostic and prognostic technology company Neoindicate LLC.

Radiopharm was unchanged at 14 cents.