Biotech Daily

Monday August 9, 2021

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: COMPUMEDICS UP 14.5%**
- CYNATA DOWN 4%

*** 4D NAMES NOVARTIS COPD PARTNER**

*** RACE DOSES 1st BISANTRENE COMBINATION AML PATIENT**

*** RESAPP EXPANDS COVID-19 TRIAL TO INDIA; LONGITUDINAL STUDY**

*** ALLEGRA, SWINBURNE, RMIT WORK ON BIOCERAMICS FOR IMPLANTS**

*** NOXOPHARM, US NCI WORK ON CANCER 'HELPER' CELL BLOCKERS**

*** RHINOMED REQUESTS 'MATERIAL CONTRACT' TRADING HALT**

*** CONTROL BIONICS TO RELEASE 81k SHARES FROM ASX ESCROW**

*** ESENSE DELISTING AGM RESOLUTIONS PASS EASILY**

MARKET REPORT

The Australian stock market was unmoved on Monday August 9, 2021, with the ASX200 constant at 7,538.4 points, the first time Biotech Daily has seen an absolute zero change in more than 15 years.

Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell and eight traded unchanged.

Compumedics was the best, up six cents or 14.5 percent to 47.5 cents, with 344,868 shares traded. Nova Eye and Universal Biosensors climbed more than seven percent; Paradigm was up 5.6 percent; Optiscan improved 4.55 percent; Alterity, Impedimed and Uscom were up more than three percent; Avita, Clinuvel, Cochlear, Nanosonics, Oncosil, Pro Medicus and Resmed rose more than one percent; with Orthocell and Telix up by less than one percent.

Cynata led the falls, down two cents or four percent to 48 cents, with 34,035 shares traded. Imugene, Next Science, Resonance and Starpharma lost more than three percent; Amplia, Antisense, Cyclopharm, Dimerix, Patrys and Prescient shed more than two percent; Genetic Signatures, Mesoblast and Neuren were down by more than one percent; with CSL, Kazia, Opthea and Proteomics down by less than one percent.

4D MEDICAL

4D Medical says it has a contract with Novartis to use its XV lung ventilation analysis software to validate drug therapies for chronic obstructive pulmonary disease.

4D said that its XV lung ventilation analysis software (LVAS) would be used to assess patient outcomes in a clinical program at Florida's University of Miami and was "the first commercial use of XV LVAS in the pharmaceutical industry".

Last week, in a carefully-worded email not released to the ASX, the company said it would trial its XV lung ventilation analysis software (LVAS) to validate "interventional pulmonary treatments", with unnamed US collaboration partners (BD: Aug 5, 2021).

4D said at that time that the interventional pulmonology, or lung treatment, market was valued at $US1.3 billion and was expected to be $US1.75 billion by 2026.

4D head of medical and clinical affairs Dr Jason Kirkness said the program would "validate approaches that use a combination of endoscopic techniques and functional lung imaging instead of surgery, offering faster diagnosis, quicker recovery time and less pain".

"In simple terms, this is a non-invasive way to visualize the extent of the diseased portions of the lung," Dr Kirkness said.

Today, the company said that COPD was the third highest cause of death in the world.

4D Medical chief executive officer Prof Andreas Fouras said the company was "extremely pleased to have secured our first pharmaceutical customer for our XV LVAS technology".

"Novartis is one of the largest pharmaceutical companies in the world and we are proud to assist them with the development of breakthrough COPD therapies," Prof Fouras said.

"The program will further validate the application of XV LVAS to improving the lives of those living with COPD, which remains a key indication for the company's technology," Prof Fouras said.

"Whilst the contract is not substantial in terms of revenue at this stage, it also represents the beginning of our commercial relationship with Novartis and expands our commercial product offering to the pharmaceutical and medical device industries," Prof Fouras said.

4D did not state any commercials terms for the contract.

4D was up 20 cents or 13.4 percent to $1.69 with 1.4 million shares traded.

RACE ONCOLOGY

Race says it has dosed the first of up-to 12 patients in its phase Ib/II trial of bisantrene in combination with two other drugs for relapsed or refractory acute myeloid leukaemia.

Race said the open-label, investigator-led trial at the Tel Aviv Chaim Sheba Medical Centre was led by Prof Arnon Nagler and would study bisantrene, renamed Zantrene, in combination with fludarabine and clofarabine, which had shown "compelling efficacy in pre-clinical studies".

Race said the two-cohort dose escalation phase would enrol three patients to receive the combination for four consecutive days and if there were no dose limiting toxicities by day 30 of their first cycle of treatment, then cohort 2 would receive the treatment for five days.

The company said the dose escalation phase would establish a maximum tolerated dose for a phase II expansion phase enrolling 17 patients.

Race said that patients would be followed every three months for 12 months and the trial was expected to take 36 to 40 months to complete, with full patient recruitment over 18 months.

Race said it would pay Chaim Sheba a total fee of $US668,739 ($A908,789) over the study's life, with payments made on reaching milestones, with the total cost dependent on the number of patients recruited.

Race fell six cents or 1.8 percent to $3.33.

RESAPP HEALTH

Resapp says it has expanded its severe acute respiratory syndrome coronavirus (Sars-Cov-2) program including longitudinal data on Covid-19 positive patients.

In March, Resapp said it hired New York's Phosphorus for to develop a smartphone-based algorithm analyzing cough sounds for Covid-19, based on its Resappdx respiratory diagnostic software (BD: Mar 11, 2021).

In May, Resapp said it enrolled the first of up-to 1,500 participants in the study, who would provide the saliva sample, an additional cough sample, return the completed kit for testing and receive the results within 48 hours (BD: May 17, 2021).

Today, Resapp said it would work with the New Delhi-based Triomics clinical trials company to begin recruitment of 100 Covid-19 positive and 100 Covid-19 negative patients in India with institutional review board approval expected "in the coming weeks" and recruitment in India expected to be completed by the end of October.

The company said that Triomics would collect longitudinal data on the Covid-19 positive patients.

Resapp managing-director Dr Tony Keating said that recent events connected to the new Delta strain of Covid-19 reinforced that "we will be living with this disease for many years to come, even with high vaccination levels" as evidenced in Israel, the UK and the US".

"This study will build upon the data we are collecting in the US and further enhance our knowledge of Covid-19 and its variants," Dr Keating said.

"Collecting further data will support our efforts to develop smartphone-based tools to instantly screen for Covid-19 as well as help healthcare providers effectively manage patients who have a Covid-19 infection," Dr Keating said

Resapp was unchanged at 4.7 cents with 1.1 million shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says it will partner with Swinburne University and the Royal Melbourne Institute of Technology to develop bio-ceramic coatings for orthopaedic implants.

Allegra said that the Federal Government-funded Innovative Manufacturing Cooperative Research Centre had awarded it $118,338 for the 12-month project led by Swinburne University's Dr Andrew Ang and Allegra's Robert Bell.

The company Allegra said it wanted to develop "a robust coating process that manufactures a new product line of bio-ceramic coated orthopaedic implants".

Allegra said the project employed a plasma spray process that enhanced bio-integration with bone tissue.

The company said the coated products would be "superior to the current market offerings".

Allegra said this industry-university collaboration will establish a solid foundation for manufacturing functional bioceramic coatings.

Swinburne's Prof Christopher Berndt said the manufacturing system was the first of its kind in Australia and would be made available to Allegra for this project".

"It will change the way orthopaedic implants are coated," Prof Berndt said.

Allegra chief executive officer Jenny Swain said that "together with our novel bio-ceramic material, this manufacturing process-material combination can expand its market within the biomedical industry".

"It could be licenced to interested coating providers," Ms Swain said.

Innovative Manufacturing Cooperative Research Centre managing-director David Chuter said that "with an ageing population and bone-related diseases on the rise, orthopaedic implants with excellent performance are needed globally".

Allegra was up half a cent or 2.3 percent to 22.5 cents.

NOXOPHARM

Noxopharm says it will work with the US National Cancer Institute on drugs for brain cancer that block glutamate from stimulating the growth of tumor cells.
Noxopharm said it had a materials cooperative research and development agreement with the National Cancer Institute, which was part of the US National Institutes of Health.
Noxopharm chief executive officer Dr Graham Kelly told Biotech Daily that the compounds were a “whole new family of molecules, distant cousins of idronoxil”.
Dr Kelly said that the Institute was “providing the funding and doing the work” with Noxopharm running its own programs in parallel.
Dr Kelly said that the National Cancer Institute had committed to a program of work, with the undisclosed budget the Institute’s responsibility.
He said the work was at the pre-clinical in-vitro stage, leading to in-vivo mouse models “but a clinical collaboration would be an obvious target for both parties should the early studies pan out”.
Noxopharm said the collaboration was based on a family of anti-cancer drugs designed by its scientists which had a “dual anti-cancer action … designed specifically for aggressive cancers including brain cancer and pancreatic cancer to block ‘helper’ signals from surrounding healthy tissue playing a key role in the aggressive cancer growth”.
The company said that ‘helper’ signals from neighboring stromal cells were “an important contributor to the highly aggressive nature of certain cancers, notably cancers of the brain, pancreas and bile duct”.
“The challenge lies in blocking these signals without damaging their source, something even more vital in the case of the brain,” Noxopharm said.
The company said that it had “achieved this objective in pre-clinical studies, combining potent killing of cancer cells with a secondary action that blocks the action of the ‘helper’ growth signals in a well-tolerated way”.
“The objective is a drug that will convert aggressive brain cancers in adults and children into slow-growing cancers more able to be effectively managed by other treatments such as surgery and radiotherapy,” Noxopharm said.
The company said that glutamate was the main helper cell in brain cancer so the objective was to block glutamate from stimulating the growth of glioma tumor cells.
The National Cancer Institute’s neuro-oncology branch principal investigator Dr Mioara Larion said the Institute was “enthusiastic about this collaboration that aims to find new targeted molecular therapies for patients affected by diseases in the central nervous system, particularly brain cancers”.
Noxopharm was unchanged at 58 cents with 1.1 million shares traded.

RHINOMED

Rhinomed has requested a trading halt “pending a material contract”.
Trading will resume on August 11, 2021, or on an earlier announcement.
Rhinomed last traded at 20 cents.

CONTROL BIONICS

Control Bionics says it will release 80,797 shares from ASX escrow on August 28, 2021.
According to Control bionics most recent Appendix 2A application for quotation of securities, after the release there would be 50,299,694 shares available for trading on the ASX, with a further 33,214,584 shares in ASX escrow.
Control Bionics fell two cents or three percent to 65 cents.

ESENSE-LAB

Esense says all 17 resolutions at its annual general meeting passed easily except for the removal of the company from the ASX which faced 6.35 percent opposition.

Esense said the resolution to be removed from the official list of the ASX was opposed by 9,263,701 votes (6.35%), with 136,613,518 votes (93.65%) in favor.

In June 25, Esense, which had been attempting to develop and commercialize marijuana "terpenes" said it proposed to be removed from the official list of the ASX "in the best interest of security holders" (BD: Jun 25, 2021).

The company said at that time that it had been suspended from trading on the ASX since July 27, 2020, following an ASX query and it required funding for its operational and working capital requirements, which since the suspension had been increasingly difficult and it had not benefited from being a listed entity.

In July, Esense said it was considering a listing on the TSX Venture Exchange of the Canadian Securities Exchange following the de-listing "where it considers the company will have greater access to capital, and shareholders will have the benefit of increased liquidity" (BD: Jul 2, 2021).

The company's most recent Appendix 2A application for quotation of securities said that Esense had 510,038,022 shares on issue, meaning that the votes against the delisted amounted to 1.8 percent of the company, not sufficient to requisition extraordinary general meetings.

Esense said that the election of external directors Deborah Gilmour and Mayaan Bar passed easily as did the election of directors Winton Willesee, James Ellingford and Peter Hatfull.

Esense remained in a suspension and last traded at 1.8 cents.