Biotech Daily

Tuesday September 20, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: IMUGENE UP 4.55%;**
- AMPLIA, NEXT SCIENCE DOWN 9%

*** COMPUMEDICS 1st SOMFIT VALIDATION SALES WORTH $200k**

*** MEMPHASYS UNDERWRITTEN RIGHTS RAISE $1.76m, TOTAL $3.4m**

*** US APPROVES ALTERITY ATH434 MULTIPLE SYSTEM ATROPHY TRIAL**

*** WASHINGTON UNI TRIALS ADHERIUM'S HAILIE SENSORS FOR ASTHMA**

*** SHINE TO SUPPLY RADIOPHARM LUTETIUM-177**

*** NEUROSCIENTIFIC: 'TRIAL REFUSED FOR SAFETY, PURITY, EFFICACY'**

*** CDA FOUNDER CALLS FOR CRONOS DIRECTORS SPILL**

*** FIL (FIDELITY) SELLS RESAPP SHARES FOR $18m**

*** CANN APPOINTS ROBERT BARNES, DR JULIAN CHICK DIRECTORS**

MARKET REPORT

The Australian stock market was up 1.29 percent on Tuesday September 20, 2022, with the ASX200 up 86.5 points to 6,806.4 points. Thirteen of the Biotech Daily Top 40 were up, 21 fell, four traded unchanged and two were untraded.

Imugene was the best, up one cent or 4.55 percent to 23 cents, with 29.6 million shares traded. Patrys improved 4.2 percent; Alcidion and Resonance climbed more than three percent; Compumedics, Medical Developments, Oncosil, Orthocell, Prescient and Pro Medicus rose two percent or more; Atomo and Neuren were up more than one percent; with CSL and Opthea up by less than one percent.

Next Science led the falls, down seven cents or 8.59 percent to 74.5 cents, with 72,291 shares traded, followed by Amplia down 0.9 cents or 8.57 percent to 9.6 cents with 327,746 shares traded.

Dimerix lost 6.9 percent; Paradigm and Starpharma were down more than five percent; Clinuvel, Impedimed and Polynovo fell more than four percent; Avita, Kazia and Telix shed more than two percent; Actinogen, Antisense, Cochlear, Pharmaxis, Proteomics and Volpara lost more than one percent; with Emvision, Genetic Signatures, Mesoblast, Nanosonics, Resmed and Universal Biosensors down by less than one percent.

COMPUMEDICS

Compumedics says it has sold about $200,000 worth of its Somfit technology platform for insomnia in Australia and Europe, starting validation of the product.

Compumedics said it had begun selling its Somfit services and product in Australia and Europe, mainly to research institutions, universities and elite sports related organizations, which would help validate the technology and generate publications in support its use.

The company said that Somfit services and product had been purchased for two insomnia studies in Australia, as well as for evaluation in occupational health and safety management in remote mining sites, for evaluation in pre-screening cardiac surgery patients and for evaluation as a patient monitor in intensive care units.

Compumedics said that it would focus on obstructive sleep apnoea home testing, sleep screening and insomnia.

Last year, the Victoria Government said it was supporting Compumedics establish a local manufacturing base for its Somfit wearable sleep and vital signs brain monitor, helping establish automated production lines and allowing the company to expand its medical device manufacturing operations, resulting in 33 new jobs over three years and targeting "an estimated export market value of $60 million over five years" (BD: Dec 7, 2021).

Compumedics executive director David Lawson told Biotech Daily at that time that the amount of Victoria Government support was "commercial in confidence".

The State Government said Somfit was a cloud-based patient monitoring system worn on the forehead, chest and wrist that remotely monitored sleep and medical conditions.

Previously, Compumedics said it was exploring the use of Somfit with Covid-19 patients (BD: Aug 26, 2021).

The company said that in August a provider of home sleep testing services in Australia signed a memorandum of understanding to evaluate Somfit services and product technology and use the technology within its current service operations, with an expectation to move 100 percent of home sleep tests to the Somfit technology over a 24-month period, beginning in January 2023, subject to evaluation milestones.

In a business update released with its preliminary final report Compumedics said it had "progressed several research and collaborative arrangements as part of the validation and commercialization of the Somfit technology … including the initial sale of about 130 devices as a result of these commercial validation activities [and was] in active discussions with interested third parties in relation to potential initial commercial applications for the Somfit device" (BD: Aug 18, 2022).

Compumedics was up half a cent or two percent to 26 cents.

MEMPHASYS

Memphasys says investors subscribed for about $900,112 in rights issue shares at two cents a share, with the underwritten shortfall raising $860,305.

Last month, Memphasys said it had commitments to raise $1.6 million in a placement at two cents a share, and had an underwritten one-for-nine rights offer at the same price to raise a further $1.76 million (BD: Aug 17, 2022).

At that time the company said it would use the funds to commercialize its Felix sperm selection device in low regulatory markets, undertake further Felix regulatory work, continue its pipeline development with the University of Newcastle, commence development of a next-generation Felix system, and pay down existing debts.

Today, Memphasys said that the shortfall of 43,015,269 shares worth about $860,305, would be taken up by lead underwriter Canaccord Genuity and sub-underwriters.

Memphasys fell 0.1 cents or 4.55 percent to 2.1 cents with 2.1 million shares traded.

ALTERITY THERAPEUTICS

Alterity says the US Food and Drug Administration has approved for its investigational new drug application for ATH434 for multiple system atrophy.
Alterity said the up-to 60-patients, phase II trial would be a randomized, double-blind, placebo-controlled study of ATH434 in patients with early-stage multiple system atrophy "a rare and highly debilitating Parkinsonian disorder".
The company said that primary endpoints were "exploring the efficacy of ATH434 treatment on neuro-imaging and protein biomarkers" as well as characterization of safety and pharmaco-kinetics of ATH434.
Alterity said that patients would receive one of two dose levels of ATH434 or placebo for 12 months and was expected to open its first trial site by the end of 2022.
The company said that the use of wearable sensors would allow evaluation of motor parameters important in patients with multiple system atrophy.
Alterity was up 0.3 cents or 20 percent to 1.8 cents with 53.3 million shares traded.

ADHERIUM

Adherium says a two-part study at Washington University School of Medicine will assess the adherence of asthma patients using its Hailie sensors for Astrazeneca's Symbicort.
Adherium said the study at the in St Louis, Missouri-based University had US National Institutes of Health funding and would use the Hailie platform and technology to assess inhaled corticosteroid adherence in 50 adults and 40 adolescents, while testing a new inhaler approach to mitigate the detrimental consequences of maintenance inhaler non-adherence.
The company said that Hailie data generation and transmission would "play a critical role in the study by measuring the use and adherence to maintenance medications while the patients are at home".
Adherium said the second phase of the study with adolescent patients would use its next generation Hailie for Symbicort HFA, its first use in a US clinical study, monitoring inhaler usage and assessing potential therapy effectiveness by analyzing inspiratory flows and other physiological parameters.
The company said that following the market launch this year for sensors capturing physiological parameters including inhalation flow rate along with adherence "this demonstrates Adherium as a global partner of choice for remote patient monitoring".
Washington University School of Medicine principal investigator Prof James Krings, said that the trial would assess "different inhaler strategies in asthma patients who are non-adherent to maintenance inhalers".
"The electronic sensors used in the trial will help to assess participants' adherence to different inhaler regimens that we are trying, which is critical to the study," Prof Krings said.
"In addition, assessing inspiratory flows may provide valuable data on day-to-day inspiratory flow and the quality of a patient's inhaler actuations, which we are excited to explore in this study," Prof Krings said.
Adherium said that the Hailie for Astrazeneca's Symbicort inhaler with physiological parameters was launched in the US in February and it recently received FDA 510(k) clearance for the inspiratory capable Hailie for Glaxosmithkline Ellipta medications and Hailie sensors had FDA 510(k) clearances for 91 percent of the US top-20 branded inhalers for monitoring adherence usage.
Adherium was untraded at 0.7 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has a clinical supply agreement with the Janesville, Wisconsin-based Shine Technology for its “isotope non-carrier-added lutetium-177”.

The company said that the lutetium-177 would be used in the development of its pipeline of diagnostic and therapeutic radio-pharmaceutical products and was currently used in multiple programs, but did not disclose the commercial terms of the agreement.

Radiopharm managing-director Riccardo Canevari said that “ensuring supply of key isotopes continues to be a priority for our team, allowing us to accelerate our clinical programs unimpeded”.

“Lutetium-177 is required for three of our more advanced assets and this clinical supply agreement with Shine, an experienced player in nuclear technology, is another important step in de-risking our business plan,” Mr Canevari said.

Radiopharm was unchanged at 17 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says ethics approval for its phase I trial of lead molecule Emtinb was refused due to a lack of safety, purity and efficacy.

Earlier this month, Neuroscientific said its Emtinb I trial was refused approval, which was followed by the resignation of managing-director Matt Liddelow (BD: Sep 7, 9, 2022).

Today, the company said the refusal was because the “local injection site tolerability was not satisfactorily demonstrated, with systemic safety not noted as a concern”, there was a “lack of clear identification of impurities and overall purity of the product was questioned [and] peptide manufacturing is complex and holds no clear guidance on overall purity requirements” and that the “key efficacy animal model was not accepted due to a different form of the Emtinb being used in this study from planned clinical product”.

Neuroscientific said that it would review the safety, purity and efficacy of Emtinb in order to submit a revised ethics application and was in discussions with two manufacturers for the further purification of available material and characterization of impurities.

Neuroscientific said it would potentially appoint an interim chief executive officer, planned to file at least two patents on Emtinb and “potentially licenced in a new technology to expand the company’s pipeline” and it would resubmit its application for a phase I trial in either Australia or an alternant geography such as the UK.

Neuroscientific was up 0.1 cents or 1.1 percent to 9.3 cents.

CRONOS AUSTRALIA

Cronos says it has received a section 249D notice calling for the removal of two directors, from a shareholder controlling more than five percent of the company.

Cronos said the board spill had been requisitioned by Matua Hasyo Charlie Jansen as trustee for the Whanau Family Trust.

The company told Biotech Daily that Dr Jansen was a founder of Cannabis Doctors Australia, which it acquired in 2021, and a former doctor with Cannabis Doctors Australia (BD: Sep 14, Dec 16, 2021).

Cronos said the resolutions called for the removal of director and chief executive officer Rodney Cocks and director and chief commercial officer Guy Headley at its next annual general meeting.

Separately, the company said it would hold its annual general meeting on November 29, 2022, and nominations for directors must be received by September 28, 2022.

Cronos was up fell 1.5 cents or 2.75 percent to 56 cents.

RESAPP HEALTH

FIL (Fidelity International Limited) Investment Management says it has sold 85,783,372 Resapp shares to Pfizer Australia for 20.8 cents a share or $17,842,941.
Last month, Pfizer Australia raised its original 11.5 cents a share offer to acquire Resapp, valuing it at about $100 million, to 20.8 cents a share valuing it at about $179 million (BD: Aug 3, 2022).
Earlier this month, Resapp said investors approved the offer and the New South Wales Supreme Court approved the scheme of arrangement (BD: Sep 8; Sep 14, 2022).
In 2016, the Hong Kong, London and Sydney-based FIL said it had become substantial in Resapp with 32,842,028 shares (5.06%) buying the shares at prices ranging from 22 cents to 44 cents (BD: Jul 20, 2016).
Between 2016 and 2021, FIL bought and sold shares in Resapp at prices ranging from 5.16 cents to 49 cents a share.
In 2021, the company said it bought 25,897,402 shares in a placement at 5.8 cents a share (BD: Apr 22, 2021).
Resapp has been suspended and last traded at 20.5 cents.

CANN GROUP

Cann Group says it has appointed Robert Barnes and Dr Julian Chick as directors, with Mr Barnes' appointment effective immediately and Dr Chick starting on October 26, 2022.
Cann Group said that Mr Barnes had worked in pharmaceuticals, food additives, infant formula, consumer, medical devices and diagnostics industries, for companies including Aspen Pharmacare Australia, Sanofi Australia and Mayne Group.
The company said Mr Barnes has been a company director and according to his Linkedin page held a Bachelor of Medical Science and a Master of Business Administration from Royal Melbourne Institute of Technology.
Cann Group said that Dr Chick had more than 25 years' experience in the biotechnology and medical technology sectors and previously was an executive with Avexa and Admedus (now Anteris) and was currently the chair of Opyl AI, formerly Shareroot.
The company said Dr Chick held a Bachelor of Science and a Doctor of Philosophy from Melbourne's La Trobe University.
Cann Group fell half a cent or 1.9 percent to 26 cents.