Biotech Daily

Tuesday May 9, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PATRYS UP 17%; COMPUMEDICS DOWN 6%**

*** VICTORIA $5m FOR 23 PROJECTS**

*** VICTORIA $500k FOR BIONICS INST EARGENIE KIDS HEARING MONITOR**

*** AVECHO RIGHTS RAISE $2m OF HOPED-FOR $11m**

*** CLINUVEL TAKES PRÉNUMBRA TRIAL TO MODERATE-SEVERE STROKE**

*** RADIOPHARM RAD301 PANCREATIC CANCER FDA ORPHAN DRUG STATUS**

*** CYCLOPHARM PREPARES FOR FDA INSPECTION**

*** AMPLIA RECRUITS 3rd AMP945 PANCREATIC CANCER COHORT**

*** PHARMAUST: MONEPANTEL BROAD ANTI-CANCER EFFECT, IN-VITRO**

*** FIREBRICK: CANADA ALLOWS NASODINE PATENT**

*** SIGNATURE ONCOLOGY APPOINTS GLENN GILBERT CEO, M-D**

*** RACE APPOINTS DR MICHELLE RASHFORD CMO**

*** PYC REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** VIBURNUM TAKES 5% OF MAYNE PHARMA**

MARKET REPORT

The Australian stock market fell 0.17 percent on Tuesday May 9, 2023, with the ASX200 down 12.4 points to 7,264.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and one was untraded. All three Big Caps fell.

Patrys was the best, up 0.2 cents or 16.7 percent to 1.4 cents, with 6.4 million shares traded. Amplia climbed 10 percent; Impedimed improved 9.1 percent; Imugene was up 8.7 percent; Uscom climbed six percent; Mesoblast was up 5.6 percent; Atomo and Cyclopharm were up more than three percent; Kazia, Nova Eye and Volpara rose more than two percent; Actinogen and Micro-X were up more than one percent; with Genetic Signatures up by 0.75 percent.

Compumedics led the falls, down one cent or 6.25 percent to 15 cents, with 25,157 shares traded. Universal Biosensors lost six percent; Paradigm was down 5.2 percent; Antisense fell four percent; Medical Developments, Prescient and Starpharma were down more than three percent; Avita, Emvision, Immutep, Opthea, Polynovo and Telix shed more than two percent; Clinuvel, Orthocell and Pharmaxis lost more than one percent; with Cochlear, CSL, Neuren, Next Science, Pro Medicus and Resmed down less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says it will grant $5,075,438 through its Medical Research Acceleration Fund to 23 biotechnology and medical research projects.
A media release from Victoria Minister for Medical Research Mary-Anne Thomas said that $500,000 would support the Eargenie trial, fitting babies with a headband to diagnose potential hearing difficulties (see below).
The Government said that Monash University would be supported with $498,489 to research the use of inhaled oxytocin to reduce maternal mortality.
The media release said the Murdoch Children's Research Institute at the Royal Children's Hospital would receive $666,061 for three projects, including mental health in schools, alleviating stress in young trans-sexual people and delivering culturally tailored vaccine education for Arabic-speaking Victorians.
The Government said Sleeptite would receive $500,000 for research with the Royal Melbourne Institute of Technology into non-invasive technology to manage the risk of pressure injuries; Breast Screen Victoria would receive $500,000 for work with Monash University on artificial intelligence analysis of mammogram readings; and the Hudson Institute would receive $470,000 for treatments for severe lung infections.

VICTORIA GOVERNMENT, BIONICS INSTITUTE

The Victoria Government says it will grant $500,000 to the Bionics Institute to support a trial of the Eargenie paediatric hearing monitor.
A media release from the Victoria Minister for Medical Research Mary-Anne Thomas said that early intervention was critical in the development of babies, and the Victorian Medical Research Acceleration Fund $500,000 would support the Eargenie trial, fitting babies with a headband to monitor their response to different sounds.
The Government said that babies found to be deaf or hard of hearing could be provided with the right hearing aids as early as possible.
The State Government said that currently, babies had to wait until they were nine months old before audiologists could determine if their treatment was helping.
"If the treatment isn't right in the first months of life, they never catch up with their peers," the media release said.
"Choosing the right treatment at the earliest time will give hearing impaired babies the ability to hear and distinguish between the sounds that teach them to speak," the media release said.
"Every second counts in a baby's development and the Eargenie could lead to early intervention for babies with hearing difficulties, giving them the best chance of hearing clearly and learning to speak," Ms Thomas said.
In a separate announcement the Bionics Institute Eargenie research team leader Prof Colette McKay said the technology comprised a soft band using near-infrared light sources and light detectors, wrapped around the baby's head while asleep.
"When a sound is played, software records the brain's response through changes in the reflected light, which help audiologists to select an appropriate hearing aid or know when to refer the baby for a cochlear implant," Prof McKay said.
"Choosing the right treatment at the earliest time will give hearing impaired babies the ability to hear and distinguish between the sounds that teach them to speak and give them the best chance to succeed in life," Prof McKay said.
The Bionics Institute said it was seeking infants under the age of 24 months to participate the trials so the technology could be developed for use in clinics as quickly as possible.
For more information, go to: https://bit.ly/3HNG4fu.

AVECHO BIOTECHNOLOGY

Avecho says it has raised about $2 million of a hoped-for $11 million in a one-for-one, rights offer at 0.6 cents a share, and it may place the $9 million shortfall.
Last month, Avecho said it hoped to raise $11 million in the rights offer, with three attaching options for every two shares bought under the offer, exercisable at 1.2 cents a share within three years (BD: Apr 3, 2023).
At that time, the company said the funds would be used to progress its phase III trial of its tocopheryl phosphate mixture oral marijuana product for insomnia.
Today, Avecho said the offer was not underwritten so the remaining shortfall of about 1.5 billion shares, or $9 million, might be placed by the company.
Avecho chief executive officer Dr Paul Gavin said existing shareholders had expressed an "indicative interest" to subscribe for a further $1 million in the shortfall placement.
Avecho fell 0.05 cents or 10 percent to 0.45 cents with 10.3 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has expanded its study of Prénumbra, or afamelanotide, from mild-to-moderate stroke patients to moderate-to-severe and severe stroke patients.
In March, Clinuvel said it had dosed the first of 12-patients in its 42-day, phase II trial of Prénumbra Instant for arterial ischaemic strokes to evaluate the safety and efficacy of the drug in patients illegible for standard-of-care treatment (BD: Mar 20, 2023).
Today, the company said its hormone analogue, brain tissue protecting, anti-oxidant and anti-swelling drug afamelanotide for ischaemic strokes was well tolerated in all three mild-to-moderate stroke patients, with functional improvement observed after dosing.
Clinuvel head of clinical operations Dr Pilar Bilbao said the company had "gradually widened the envelope of afamelanotide, providing data on its safety profile which have remained remarkably constant".
"This chosen strategy allows us to use the molecule for a wide range of metabolic and neurological conditions with different formulations and dosing frequencies," Dr Bilbao said.
Clinuvel fell 31 cents or 1.6 percent to $19.56 with 66,050 shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has US Food and Drug Administration orphan drug status for its gallium-68-Trivehexin, or RAD301, for pancreatic ductal adenocarcinoma imaging.
Radiopharm said Trivehexin was a radiopharmaceutical for imaging and treating pancreatic cancer that used a proprietary peptide-based molecule that targeted a cellular marker for tumor invasion with metastatic growth.
The company said it had an exclusive licence with Trimt GmbH for the development and commercialization of RAD301 in the US, China, Australia, Hong Kong and Japan.
Radiopharm chief executive officer and managing director Riccardo Canevari said "Orphan drug designation for RAD301 comes on top of investigational new drug approval for a phase I clinical trial in pancreatic cancer, which is planned to start in the next few weeks".
"The FDA's decision highlights the significant demand for effective imaging agents for improved and earlier diagnosis of pancreatic cancer, which ash one of the highest levels of unmet needs among all cancer types," Mr Canevari said.
Radiopharm fell 0.5 cents or 2.9 percent to 16.5 cents.

CYCLOPHARM

Cyclopharm says the US Food and Drug Administration will inspect its Sydney Technegas manufacturing facility between July 24 and August 4, 2023.
In March, Cyclopharm said it had filed its response to the US Food and Drug Administration complete response letter, which refused approval of Technegas for lung imaging (BD: Mar 30, 2023).
Today, the company said the inspection followed the FDA's six-month review period confirmation, ending September 29, 2023, for its Technegas new drug application and advised a site visit was expected during the period.
Cyclopharm chief executive officer James McBrayer said he was pleased the inspection fell within the FDA's goal review period.
Cyclopharm was up eight cents or 3.9 percent to $2.15.

AMPLIA THERAPEUTICS

Amplia says it has enroled the third cohort of patients in its phase Ib/IIa, ascending dose trial of AMP945 with chemotherapy for advanced pancreatic cancer.
Last year, Amplia said it had dosed the first of 12 patients in the open-label trial, studying the pharmaco-kinetics, safety and efficacy of AMP945 in combination with nab-paclitaxel (Abraxane) and gemcitabine for pancreatic cancer (BD: Aug 2, 2022).
At that time, the company said the trial was an ascending dose, single-arm, open-label study across cohorts of three patients assessing safety, tolerability, pharmaco-kinetics, pharmaco-dynamics and preliminary efficacy of AMP945 in combination with gemcitabine and nab-paclitaxel, in first-line patients with advanced pancreatic cancer.
Today, Amplia said that after one month of treatment the trial's safety committee would review the clinical data collected and determine the next steps in the trial.
Amplia chief executive officer and managing director Dr Chris Burns said the achievement reflected "the enthusiasm and commitment of the clinical trial sites in Melbourne, Sydney and Brisbane" which completed recruitment a month from opening enrolment.
Amplia was up one cent or 10 percent to 11 cents.

PHARMAUST

Pharmaust says monepantel "has broad anti-cancer effects across multiple cancer types [including] melanoma, lung, breast, brain, colorectal, prostate and ovarian", in-vitro.
Pharmaust said that research at Melbourne's Olivia Newton John Cancer Research Institute showed that monepantel could "stop the growth of many types of cancer cells" through cell death, apoptosis, or disrupting cell reproductive cycles, and autophagy.
The company said the study, titled 'Induction of endoplasmic reticulum stress in associated with the anti-tumor activity of monepantel across cancer types' was published in the journal Cancer Medicine and the full article was available at: https://onlinelibrary.wiley.com/doi/10.1002/cam4.6021.
The article said that monepantel had anti-proliferative activity on a broad range of cancer cell lines using in-vitro viability assays on more than 20 solid cancer cells and apoptosis assays were performed on a subset of those cells, including three-dimensional cultures.
Pharmaust executive chairman Dr Roger Aston said the analysis "of the mechanisms of action of monepantel in conjunction with its very low toxicity offers a potential new paradigm in the regulation and management of cancer".
Pharmaust was unchanged at 8.1 cents with 3.5 million shares traded.

FIREBRICK PHARMA

Firebrick says its core patent covering Nasodine nasal spray as a treatment and preventative for the common cold has been allowed in Canada.
Firebrick said the patent, titled 'Treatment and prevention of the common cold using povidone-iodine' protected its intra-nasal Betadine-based Nasodine in most countries until 2035 and in Australia until 2034.
The company said once the patent was granted it would bring the number of countries with the patent granted to 28 in North America, Europe, Australia and other regions.
Firebrick was up half a cent or 2.9 percent to 18 cents.

SIGNATURE ONCOLOGY PTY LTD

Adelaide's Signature Oncology has appointed Glenn Gilbert as a consultant from today and as its chief executive officer and managing-director from June 9, 2023.
Signature said that it was developing a cancer diagnostics platform based on gene signature assays to assist clinician decision-making.
The company said that Mr Gilbert would be "an exclusive consultant … while the company completes a capital raise to fund the next development phase of its proprietary gene signature melanoma diagnostic".
Signature said that following completion of the capital raise, Mr Gilbert would assume the role of chief executive officer and managing-director.
The company said that Mr Gilbert had more than 18 years of experience in the healthcare sector, including pharmaceutical, medical device and in-vitro diagnostics.
Signature said that Mr Gilbert was most recently Rhythm Biosciences managing-director developing low cost, blood tests for cancer detection (BD: Apr 19, 2023).
The company said that previously, Mr Gilbert was an executive at CSL Seqirus and Medical Developments, with business experience in the UK, Europe, Asia, North and South America.
Signature Oncology is a private company.

RACE ONCOLOGY

Race says it has appointed Dr Michelle Rashford chief medical officer, replacing interim chief medical officer Dr Ajay Duggal, effective FROM July 1, 2023.
Last year, Race said Dr Duggal was appointed interim chief medical officer replacing Dr David Fuller, who resigned to join Aucentra Therapeutics (BD: Nov 11, 2022).
Today, the company said Dr Rashford was currently the Tokyo-based Kyowa Kirin's head of clinical studies and previously was the Hangzhou City, Zhejiang Province, China-based Adlai Nortye Biopharma's head of clinical science and had worked for Bristol-Myers Squibb and Roche.
Race said Dr Rashford held a Bachelor of Medicine and Bachelor of Surgery from the University of Tasmania.
Race fell three cents or 1.6 percent to $1.84.

PYC THERAPEUTICS

PYC says it has requested a trading halt "pending an announcement to the market regarding a proposed capital raising".
Trading will resume May 11, 2023, or on an earlier announcement.
PYC last traded at 6.4 cents.

MAYNE PHARMA

Viburnum Funds Pty Ltd says it has become a substantial shareholder in Mayne Pharma with 4,362,521 shares, or 5.13 percent.

The Nedlands, Western Australia-based Viburnum said that between April 21 and May 8, 2023 it bought 511,541 shares for $2,077,395, or $4.06 a share.

Last year, Mayne conducted a 20-to-one consolidation (BD: Nov 30, 2022).

Mayne Pharma fell 13 cents or 3.1 percent to $4.11.