



Biotech Daily

Monday September 21, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: AMPLIA UP 7%; ANTISENSE DOWN 23%**
- * **TELIX DOSES 1st 89-ZR-APOMAB LUNG, OVARIAN CANCER PATIENTS**
- * **AZURE READY FOR IVB003 TOCOTRIENOL PANCREATIC CANCER TRIAL**
- * **FEDERAL \$3m FOR 2 DOHERTY-MIPS COVID-19 VACCINE CANDIDATES**
- * **TBG: MEDIGEN DISTRIBUTES SARS-COV-2 TEST KITS**
- * **ADALTA PROGRESSES GE HEALTHCARE I-BODY COLLABORATION**
- * **RESAPP REQUESTS FDA SLEEPCHECK PRE-SUBMISSION MEETING**
- * **PHARMAUST: \$881k FOR MONEPANTEL FOR MOTOR NEURON DISEASE**
- * **CRESO: NOVA SCOTIA LIQUOR CORP ORDERS \$187k MARIJUANA**
- * **INVION DIRECTOR SHARES, OPTIONS IN LIEU OF CASH AGM**
- * **RECCE REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **THC REQUESTS 'FEDERAL COURT ORDERS' TRADING HALT**
- * **OPTISCAN REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **ALLAN GRAY REDUCES TO 12% OF STARPHARMA**
- * **CONSTELLATION, LISHAN ZHANG BELOW 5% IN ANTERIS**
- * **OPYL: MARK ZIIRSEN DIRECTOR, DAMON RASHEED EXECUTIVE**
- * **AUSCANN LOSES DIRECTOR DR MARCEL BONN-MILLER**

MARKET REPORT

The Australian stock market fell 0.71 percent on Monday September 21, 2020, with the ASX200 down 41.9 points to 5,822.6 points. Nine of the Biotech Daily Top 40 stocks were up, 22 fell, eight traded unchanged and one was untraded.

Amplia was the best, up one cent or 6.7 percent to 16 cents, with 562,225 shares traded. Actinogen climbed 3.6 percent; Imugene, Pharmaxis and Pro Medicus rose more than two percent; Clinuvel and Mesoblast were up one percent or more; with Avita, Cochlear, CSL and Neuren up by less than one percent.

Antisense led the falls on no news, down three cents or 23.1 percent to 10 cents, with 4.6 million shares traded. Immutep lost 15.25 percent; Alterity and Oncosil shed more than seven percent; Cyclopharm and Medical Developments fell more than five percent; Prescient and Universal Biosensors lost more than four percent; Orthocell and Resonance fell more than three percent; Cynata, Kazia, Nova, Paradigm, Starpharma and Telix shed two percent or more; Genetic Signatures, Nanosonics and Volpara lost one percent or more; with Next Science, Opthea, Polynovo and Resmed down by less than one percent.

TELIX PHARMACEUTICALS

Telix says it has dosed the first two patients in its 18-patient, phase I trial of zirconium-89-Apomab, for advanced lung and ovarian cancer.

Telix said the two-arm, proof-of-concept study, at the Royal Adelaide Hospital, would be co-funded by the company and its strategic partner the Central Adelaide Local Health Network owned Aushealth, formerly Medvet.

An Aushealth executive told Biotech Daily that Apomab was invented by the Royal Adelaide Hospital's Prof Michael Brown in collaboration with the then Medvet.

The executive said that Aushealth delivered health and safety services including alcohol and drug testing to commercialize research.

Telix said it would use positron emission tomography to evaluate how well Apomab could deliver diagnostic and therapeutic targeted radiation to advanced lung or ovarian cancers.

Telix said Apomab targeted the La Sjogren syndrome antigen B (La/SSB) protein, specifically expressed by cancer cells treated with chemotherapy and/or radiation.

Principal investigator Prof Brown said that "the dosing of these first patients is the culmination of more than a decade of fundamental research around a novel oncology target and enables the evaluation of the potential of Apomab as a targeting agent for imaging and therapy".

Telix chief executive officer Dr Chris Behrenbruch said the study would test the suitability of the Apomab technology to deliver targeted radiation to lung and ovarian cancers "two areas of cancer care where there is a significant unmet medical need to provide patients with additional therapeutic options".

Telix fell four cents or 2.2 percent to \$1.76.

AZURE HEALTH TECHNOLOGY

Azure says it has prepared the protocol for an 80-patient, phase II study of its tocotrienol-based, buccal and sub-lingual IVB003 for pancreatic cancer.

Azure said it proposed a randomized, double-blind, placebo-controlled trial, at up-to 10 sites in Australia, to assess the efficacy and safety of 60mg IVB003 three times daily using its transmucosal delivery platform, for the vitamin E derived tocotrienol compounds.

The company said the active pharmaceutical ingredient was a formulation of predominantly delta tocotrienol with gamma tocotrienol, which had been demonstrated in a previous phase Ia study to be delivered efficiently transmucosally, achieving improved bioavailability compared to orally administered tocotrienols.

Azure said patients with locally advanced or metastatic pancreatic cancer would be randomized to standard-of-care plus self-administered sublingual IVB003 or placebo, and followed until disease progression, toxicity or the investigator's decision to stop therapy.

The company said the primary endpoints would be progression-free survival and objective response rate between the IVB003 and placebo groups.

Azure said that the secondary endpoint would be overall survival, along with rates of complete response, partial response, stable disease and progressive disease, and the decrease in pancreatic cancer tumor marker CA19-9.

The company said that with Sydney-based clinical research organization Datapharm Australia it was selecting clinical study sites.

Azure chief scientific officer Dr David Kingston said support from key opinion leaders and a formal pre-investigational new drug application consultation with the US Food and Drug Administration provided "a high level of confidence that there is a compelling case for conducting this clinical study".

Azure is a public unlisted company.

FEDERAL GOVERNMENT, PETER DOHERTY INSTITUTE MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

The Doherty Institute says the Federal Government has provided \$3 million for two severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) vaccine candidates.

The Doherty said that the grant from the Medical Research Future Fund were for a receptor binding domain protein and a receptor binding domain messenger RNA.

The Institute said the two vaccine candidates were developed researchers from the Doherty and the Monash Institute of Pharmaceutical Sciences (MIPS) and had provided encouraging pre-clinical results.

Doherty immunology theme leader Prof Dale Godfrey said the vaccine approaches were “very different to the two Australia-based candidates currently in clinical trials”.

“Sars-Cov-2, the virus that causes Covid-19, is enveloped by proteins that resemble spikes, which enable the virus to attach and enter cells,” Prof Godfrey said.

“This attachment is mediated by the tip of the spike protein, known as the receptor binding domain,” Prof Godfrey said.

“Our vaccine candidates focus specifically on the [receptor binding domain] because if we can block this attachment, we can block infection,” Prof Godfrey said.

“The spike protein is viewed as the most important target for antibodies produced by the immune system because most antibodies that neutralize the virus do so by targeting the [receptor binding domain] region of the spike.”

The Doherty said the first of the two candidates was the receptor binding domain (RBD) protein, which represented the tip of the spike in an isolated molecular form to focus the immune response on this region of the virus targeted by antibodies that neutralized viral infectivity.

The Institute said the second candidate was the RBD messenger RNA which “represents the virus genetic sequence that codes for the tip of the spike, which will lead to production of the RBD protein”.

Monash University’s Prof Colin Pouton said his group’s approach included messenger RNA technology “which should provide a very safe and focussed vaccine with the important ability to rapidly adjust its composition in response to emerging virus mutations”.

“If the virus mutates, a new vaccine can be tested within a few weeks,” Prof Poutin said.

Doherty Institute director Prof Sharon Lewin said the Federal Government funds would expedite the vaccine approach “hopefully entering phase I human trials quickly”.

The Institute said that the project was supported by CSL vaccine manufacturer, Seqirus.

TBG DIAGNOSTICS

TBG says that through TBG Taiwan it has a distribution agreement with Medigen to distribute its severe acute respiratory syndrome-coronavirus-2 (Sars-Cov-2) test kits.

TBG said that Taipei’s Medigen Biotechnology Corp was its parent company and according to the ASX, owned 48.7 percent of TBG, of which TBG Taiwan was a wholly owned subsidiary.

The company said Medigen had been TBG Taiwan’s primary distributor since 2015 and would now include its Sars-Cov-2 rapid test kit and nucleic acid test kit.

The company said it would manufacture the test kits and Medigen would pay an amount equal to 50 percent of the net profit, as well as manufacturing costs, for exclusive distribution rights.

TBG said the agreement was for three years from February 15, 2020 and it had generated \$270,725 from sales through Medigen since August 31, 2020.

TBG was in an ASX suspension and last traded at 27 cents.

ADALTA

Adalta says it has progressed its multistage collaboration with the Chicago-based GE Healthcare to further characterize “i-bodies” antibodies.

Last year, Adalta said it had a commercial agreement with GE Healthcare for its i-body platform to develop diagnostic imaging (BD: Sep 16, 2019).

The company said its i-body technology was “a new class of human protein therapeutic”, named from the “intermediate” of four groups of immunoglobulin or immunoglobulin-like domains, based on the shape of the shark single domain antibody and one tenth the size of traditional antibodies (BD: Jul 7, 2016).

Today, Adalta said that to date, it had discovered a panel of i-bodies that warranted further development and had earned an initial milestone payment and research fees for the first three stages of the collaboration.

The company said undisclosed research fees for stage four would be paid in instalments over six months, beginning in November 2020.

Adalta was up half a cent or five percent to 10.5 cents with 4.1 million shares traded.

RESAPP HEALTH

Resapp says it has requested a US Food and Drug Administration pre-submission meeting for its Sleepcheck mobile application for obstructive sleep apnoea.

Resapp said it had filed a pre-submission package for Sleepcheck, which assessed the risk of obstructive sleep apnoea by analyzing breathing and snoring sounds during sleep.

The company said it had scheduled a pre-submission meeting for November 2020 in order to discuss the 510(k) pathway for Sleepcheck.

Resapp was unchanged at 11 cents.

PHARMAUST

Pharmaust says it has received an \$881,085 grant for a phase I trial of monepantel for motor neuron disease from the charity Fight MND.

Pharmaust has previously trialed monepantel, the Elanco sheep round-worm drench, for cancer in humans and dogs, and has recently made several announcements claiming pre-clinical efficacy for severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) the virus that caused Covid-19 (BD: May 12, Jun 4, 2020).

Today, the company said the trial would recruit people at the Parkdale, Melbourne-based Calvary Health Care Bethlehem and Sydney’s Macquarie University.

Pharmaust said motor neuron disease was a rare and invariably fatal neurological disease and the current best treatment attempted to control disease progression and manage symptoms.

The company said it was hypothesized that monepantel benefited the health of neural cells by regulating problems associated with intracellular proteins, which reduced motor neuron disease-associated symptoms.

Pharmaust said the funds from Fight MND would be used to manufacture monepantel, to assess trial participants and to contract an independent clinical trial organization for trial management.

The company said it had commenced preparations for the trial, with recruitment to begin in early 2021.

Pharmaust was unchanged at 12.5 cents with 1.7 million shares traded.

CRESO PHARMA

Creso says it has an initial purchase order of \$C180,000 (\$A186,670) from Nova Scotia Liquor Corporation for its marijuana.

Creso said the Nova Scotia Liquor Corporation was operated by the Nova Scotia Provincial government, was the sole distributor of recreational marijuana in Nova Scotia and through Creso's wholly owned subsidiary Mernova Medicinal it had ordered two strains of its marijuana, HPG13 and Lemon Haze.

Creso was up 0.6 cents or 18.2 percent to 3.9 cents with 14.5 million shares traded.

INVION

Invion says its annual general meeting will vote to issue shares to chief executive officer Craig Newton and options to non-executive directors, in lieu of cash payments.

Invion said it would vote to issue Mr Newton \$256,151 in shares as consideration for deferred salary payments from November 1, 2019 to October 31, 2020, based on a 14-day volume weighted average price (VWAP).

The company said it would also issue Mr Newton 6,814,404 options worth \$48,382 under its employee share option plan.

Invion said the options would vest immediately and would be exercisable at the 14-day VWAP by October 31, 2024.

The company said it would vote to issue options worth \$27,500 and \$22,810 respectively to directors Thian Chew and Alan Yamashita in lieu of a cash payment for directors' fees from April 1 to August 31, 2020, exercisable at the 14-day VWAP by October 31, 2024.

Invion said it would also vote to issue further options, amounting to \$90,000 for Mr Chew and \$54,740 for both Rob Merriel and Mr Yamashita, in lieu of a cash payment for fees from September 1, 2020 to August 31, 2021 on the same terms.

The company said it would vote to adopt its remuneration report, to elect Rob Merriel as a director and to re-elect director Alan Yamashita, along with special resolutions to approve a 10 percent placement capacity and to renew rule 27 of its constitution for proportional takeover bids.

The meeting will be held virtually on October 21, 2020 at 3pm (AEDT).

Invion fell 0.1 cents or 10 percent to 0.9 cents with 2.8 million shares traded.

RECCE PHARMACEUTICALS

Recce has requested a trading halt "pending the release of an announcement relating to a capital raising".

Trading will resume on September 23, 2020 or on an earlier announcement.

Recce last traded at \$1.635.

THC GLOBAL GROUP

THC has requested a trading halt pending an announcement "with respect to orders being sought from the Federal Court of Australia in relation to the June 2020 placement".

In June, THC said it had raised \$6.6 million through a placement to institutional and sophisticated investors at 30 cents a share and in July, said it had raised \$1,535,000 through a share purchase plan at the same price (BD: Jun 22, Jul 17, 2020).

Trading will resume on September 23, 2020 or on an earlier announcement.

THC last traded at 26.5 cents.

OPTISCAN IMAGING

Optiscan has requested a trading halt “pending an announcement by the company to the market regarding a capital raising”.

Trading will resume on September 25, 2020 or on an earlier announcement.

Optiscan last traded at 10.5 cents.

STARPHARMA HOLDINGS

Allan Gray Australia says it has reduced its substantial shareholding in Starpharma from 48,891,666 shares (13.12%) to 45,058,767 shares (12.09%).

The Sydney-based Allan Gray said that between September 3 and 16, 2020 it sold 3,832,899 shares for \$6,526,202 or an average \$1.70 a share.

Starpharma fell 4.5 cents or 2.65 percent to \$1.655 with 695,450 shares traded.

ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

Constellation International and Lishan Zhang say they have ceased to be substantial holders in Anteris, reducing from 730,192 shares (12.35%) to 259,699 shares (4.39%).

In July, the Star Bright Group, comprising Star Bright Holding, Constellation International, Constellation Immunotherapy, Carron Services and former Admedus director Lishan Zhang, said it had reduced its holding in Anteris from 1,277,155 shares (21.61%) to 730,192 shares (12.35%) (BD: Jul 17, 2020).

Also in July, Constellation Immunotherapy, Everbest City and Fung Yuen Wong (Everbest Group) said they had become substantial in Anteris with 326,951 shares (5.53%) and the next day, ceased to be substantial holders (BD: Jul 20, 21, 2020).

Today, the Hong Kong-based Constellation and Ms Zhang said that on September 15, 2020 it disposed of 493 shares for \$1,942 and on September 16, disposed of 470,000 shares for \$HK8,930,000 (\$A1,573,233).

Anteris was up five cents or 1.25 percent to \$4.05.

OPYL

Opyl says it has appointed Mark Ziirsens as a non-executive director, Damon Rasheed, appointed an executive director.

Opyl said Mr Ziirsens would replace Mr Rasheed as chair of its audit and risk committee. The company said that Mr Ziirsens was most recently the chief financial officer and company secretary of Wiseway Group, following roles as a director of Respiro and chief financial officer of Anteris (then Admedus) and previously the director of finance and information technology for the Asia Pacific at Cochlear.

Opyl said that Mr Ziirsens previously held financial roles at Aristocrat Leisure, Coca-Cola Amatil and Goldman Fielder.

Opyl said Mr Ziirsens held a Bachelor of Commerce from the University of Queensland and a Master of Business Administration from the University of New England.

Opyl was up one cent or 4.55 percent to 23 cents.

AUSCANN GROUP HOLDINGS

Auscann says non-executive director Dr Marcel Bonn-Miller has resigned effective from October 3, 2020.

Auscann said Dr Bonn-Miller joined the company in October 2019 as a representative director for Canopy Growth and continued after Canopy sold its holding to Merchant Capital (BD: Oct 14, 2019).

Auscann was unchanged at 15 cents.