Biotech Daily

Wednesday September 15, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MEDICAL DEVELOPMENTS UP 6%; IMPEDIMED DOWN 8%**

*** REDHILL: OPAGANIB PHASE II/III MISSES COVID-19 ENDPOINTS**

*** IDT: $11.5m FOR FEDERAL STERILE DRUG MANUFACTURE PLANT**

*** AMPLIA 1st LINE AMP945 COMBINATION PANCREATIC CANCER TRIAL**

*** TELIX SUPPLIES ILLUCCIX TO AMGEN FOR PSMA THERAPY TRIAL**

*** PATRYS: 'PAT-DX3- MMAE REDUCES BREAST CANCER GROWTH, IN MICE'**

*** NUHEARA: REGISTRATION-DIRECTED HEARING AID TRIAL**

*** AVECHO RECRUITS 1st PHASE I TPM-MARIJUANA TRIAL PATIENT**

*** ORTHOCELL: 'CELGRO ROPE IMPROVES ACL RECONSTRUCTION, IN RABBITS'**

*** IMRICOR PLEADS SCHULTZ TO ASX LISTING RULE 15.7 LEAK QUERY**

*** STARPHARMA: US PATENT FOR DEP-CABAZITAXEL**

*** CYNATA: 2 RUSSIAN PATENTS FOR CYMERUS STEM CELLS**

*** ARGENICA ARG-007 FOR STROKE SCALE-UP, PURITY**

*** SUDA NAME CHANGE TO AROVELLA, 8m DR MICHAEL BAKER OPTIONS EGM**

*** REGAL FUNDS REDUCES TO 7.4% OF ADHERIUM**

*** ATOMO APPOINTS DEBORAH NEFF DIRECTOR**

*** ADHERIUM LOSES CFO ANNE BELL; MELBOURNE CFO WANTED**

*** CHIMERIC APPOINTS 3 'CELLULAR IMMUNOTHERAPY' ADVISORS**

MARKET REPORT

The Australian stock market fell 0.27 percent on Wednesday September 15, 2021, with the ASX200 down 20.3 points to 7,417.0 points. Nine of the Biotech Daily Top 40 stocks were up, 26 fell, four traded unchanged and one was untraded. All three Big Caps rose.

Medical Developments was best, up 22 cents or 5.7 percent to $4.11, with 339,876 shares traded. Patrys climbed 5.1 percent; Starpharma improved 4.2 percent; Cynata was up 3.7 percent; Cochlear and Imugene rose more than two percent; CSL, Resmed and Telix were up more than one percent; with Avita, Paradigm and Pro Medicus up by less than one percent.

Impedimed led the falls, down one cent or 8.3 percent to 11 cents, with 6.4 million shares traded. Osprey and Prescient lost more than seven percent; LBT was down 6.9 percent; Actinogen and Optiscan fell four percent or more; Alterity, Dimerix, Nanosonics, Orthocell, Pharmaxis and Uscom were down three percent or more; Amplia shed 2.5 percent; Cyclopharm, Mesoblast, Next Science, Nova Eye and Proteomics were down more than one percent; with Clinuvel, Immutep, Kazia, Neuren, Opthea, Polynovo, Universal Biosensors and Volpara down by less than one percent.

REDHILL BIOPHARMA

Redhill says top-line data from its 475-patient trial of opaganib for Covid-19 showed "consistent trends … [but] the study endpoints did not achieve statistical significance"

Redhill said that analysis of the data was ongoing, including regarding the potential for increased benefit of opaganib in patients at earlier stages of the disease on low flow oxygen support

The company said that top-line safety data from the randomized, double-blind, parallel-arm, placebo-controlled trial showed "good tolerability with balanced adverse events between the study arms".

Redhill said that the global phase II/III study of opaganib (ABC294640) in hospitalized patients with severe Covid-19 pneumonia showed "trends in favor of the opaganib arm [versus] placebo across multiple endpoints, including the primary endpoint, despite not achieving statistical significance".

The company said that the findings, "together with preliminary analysis pointing to increased benefit in a subset of patients requiring less oxygen, could support the potential utilization of opaganib in earlier stages of the disease and are in line with the previously announced results from the US phase II study and the previously observed anti-viral activity of opaganib".

Redhill chief executive officer Dror Ben Asher said: "While we are disappointed with the data not reaching statistical significance, we do see a trend that needs to be investigated that opaganib may provide benefit to patients earlier in the course of the disease".

"This correlates with what we know about opaganib's strong anti-viral mechanism and effect against variants, as well as its mechanism of action and previously announced results from the phase II US study with opaganib," Mr Ben Asher said.

On the Nasdaq, Redhill fell $US2.41 or 32.66 percent to $US4.97 ($A6.79) with 7,241,662 shares traded.

IDT AUSTRALIA

IDT says that the total cost of recommissioning its sterile drug manufacturing facility for the Federal Government is $11,446,250.

In August, IDT said it had a Sterile Readiness Agreement with the Federal Department of Health to recommission its Melbourne sterile manufacturing facilities for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) vaccines (BD: Aug 23, 2021).

The company said at that time that it had agreed to ensure the production capacity of its sterile facility would be exclusively for the Federal Department of Health or its nominee until the earlier of executing a supply agreement to deliver a vaccine, or four months from completion of the sterile readiness works.

Today, IDT said that it received $7,500,000 in the year to June 30, 2021 and the remaining work related to sterile facility recommissioning and sterile readiness works, which were "nearing completion".

The company said that it would maintain the facility in a sterile state, exclusively for the Federal Department of Health, which could nominate a severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) vaccine, in which case IDT and the relevant vaccine company would need to agree on commercial terms for the manufacture of the vaccine.

IDT said its facilities were clinical good manufacturing practice compliant and audited by the US Food and Drug Administration and Australian Therapeutic Goods Administration.

In August, the Victoria Government said a $1 million Nanoassemblr has been shipped to IDT to manufacture the final product for mRNA vaccines (BD: Aug 23, 2021).

IDT was up 4.5 cents or 7.1 percent to 67.5 cents with 2.4 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it will begin a 64-patient combination trial of its focal adhesion kinase inhibitor AMP945 with chemotherapy as a first-line therapy for pancreatic cancer in 2022.

Amplia said the open-label trial would be in two stages with oral AMP945 given to patients prior to each dose of gemcitabine/nab-paclitaxel chemotherapy, the standard-of-care used for the majority of newly-diagnosed advanced pancreatic cancer patients.

The company said the first stage involving 40 patients, would select an optimal dose of AMP945 and conduct a preliminary assessment of efficacy.

Amplia said the second stage would recruit up to an additional 24 pancreatic cancer patients to expand the trial to increase confidence in the preliminary results.

The company said all patients were expected to receive multiple rounds of treatment.

Amplia said the design of the trial was based on studies conducted with the Garvan Institute, which showed that intermittent dosing of AMP945 made tumors more responsive to standard chemotherapy treatments for pancreatic cancer in mice (BD: Jun 2, 28, 2021).

The company said it planned to begin recruitment by April 2022 and take up to two years.

Amplia said the primary endpoint would be “based on the objective response rate from treatment compared to historical controls” with secondary endpoints including duration of response, disease progression rates, survival and effects on biomarkers.

Amplia chief executive officer Dr John Lambert said that evaluation of AMP945 as part of a first-line treatment for pancreatic cancer “significantly de-risks the program and makes the drug relevant for a much larger patient base”.

“If we are able to see positive signs that AMP945 improves the leading current treatment option we will commence discussions with regulators and potential partners concerning future trials required to support product approval,” Dr Lambert said.

Amplia fell half a cent or 2.5 percent to 19.5 cents.

TELIX PHARMACEUTICALS

Telix says it is supplying Illuccix to support a prostate specific membrane antigen (PSMA) targeted imaging study by the Thousand Oaks, California-based Amgen Inc.

Telix said Amgen’s study of the acaptamab antibody for prostate cancer treatment was under an agreement with Invicro LLC, a US-headquartered contract research organisation and subsidiary of Konica Minolta.

Telix chief executive officer, Dr Christian Behrenbruch said the agreement showed “both the strength and reliability of Telix’s supply chain globally and validates the potential of our Illuccix prostate cancer imaging candidate in support of a wide range of PSMA-targeting therapies”.

Telix was up eight cents or 1.2 percent to $6.95 with 596,269 shares traded.

NUHEARA

Nuheara says it has approval for a 50-patient, registration-directed trial of its range of hearing aid products.

Last month, Nuheara said Sydney’s National Acoustics Laboratories was planning clinical trials of its hearing aid products to test the safety and efficacy (BD: Aug 17, 2021).

Nuheara managing-director Justin Miller said that National Acoustics Laboratories had begun recruiting for the clinical trial.

“Receiving regulatory approval will open substantial new market opportunities for Nuheara in the US, Europe and Australia,” Mr Miller said.

Nuheara fell 0.1 cents or 3.3 percent to 2.9 cents with two million shares traded.

PATRYS

Patrys says its deoxymab antibodies could be used as targeting agents in antibody drug conjugates following a study which reduced breast cancer tumor growth in mice.
Patrys said it was able to conjugate the “highly potent anti-cancer compound” monomethyl auristatin E (MMAE) to its full-sized immunoglobulin G deoxymab antibody PAT-DX3.
The company said PAT-DX3-MMAE was given to mice implanted with the human breast cancer cell line MCF7 and “significantly inhibited tumor growth by 95 percent at day-31”.
Patrys said that MMAE was “a highly potent anti-cancer compound which, due to its extreme toxicity, can only be used when conjugated to an antibody for targeted delivery”.
The company said that unlike the antibodies used in other antibody drug conjugates, its deoxymabs did not target a specific cancer antigen, but were instead attracted to and bind to the DNA released from tumors as cancer cells died.
Patrys said the study showed deoxymabs could be used to target delivery to tumors in animals and the approach used could form the basis of antibody drug conjugates that might have utility for a broader range of cancer applications.
Patrys managing-director Dr James Campbell said the work showed that deoxymabs “can be used to target cancers and, by using a potent and validated [antibody drug conjugate] payload, deliver a drug”.
“As with the therapeutic applications we are working on, the ability of our deoxymab antibodies to target multiple types of cancer, enter the cell and cell nucleus and transit the blood brain barrier provides some really novel ways for using them as targeting agents for ADCs,” Dr Campbell said. “This study has clearly demonstrated the proof-of-concept and is expected to open up a range of potential development or partnering opportunities.”
Patrys was up 0.2 cents or 5.1 percent to 4.1 cents with 32.9 million shares traded.

AVECHO BIOTECHNOLOGY

Avecho says it has enrolled the first of 16 healthy volunteers for its phase I trial of tocopheryl phosphate mixture (TPM) soft gel marijuana-derived cannabidiol.
In April, Avecho said the trial would measure the safety and absorption profile of its cannabidiol (CBD) product using its TPM vitamin E-derived drug delivery system and the data would be used for future regulatory submissions and drug labels (BD: Apr 13, 2021).
Today, the company said the study would compare the absorption of cannabidiol from its CBD capsules at 75mg and 150mg, with results expected in December 2021.
Avecho was unchanged at 1.9 cents with 1.4 million shares traded.

ORTHOCELL

Orthocell says an anterior cruciate ligament reconstruction study in rabbits indicates that Celgro collagen rope is an alternative to autologous tendon grafts.
Orthocell said Celgro collagen rope promoted ligamentization and exhibited tissue architecture that mimicked the native anterior cruciate ligament (ACL) and integrated with the host bone tunnel.
The company said the results of this study provided evidence that Celgro collagen rope was a “potentially superior off-the-shelf alternative to current tendon autograft options in ACL reconstruction procedures”.
Orthocell said it planned to advance development of this technology and would begin a larger animal study, such as sheep, which had knee joint structure and dynamics that more closely mimics the human knee joint, before human trials.
Orthocell fell 1.5 cents or three percent to 48.5 cents.

IMRICOR MEDICAL SYSTEMS

Imricor has told an ASX "aware" query that it "has no knowledge" how the details of its $17.5 million capital raise were in a news article prior to the ASX being informed.

In recent weeks, the ASX has asked similar questions of Dimerix, Imugene and Althea in relation to the details of capital raisings leaking to the Australian Financial Review ahead of publication to the ASX (BD: Aug 16, 19, 24, 30, 2021).

The ASX said that Imricor requested a trading halt on September 7 "pending an announcement … in relation to an update in connection with a proposed capital raise" at 8.50am (AEST) (BD: Sep 7, 2021).

The ASX said that an article titled 'MA Moelis, Bell Potter tapped for Imricor's $17.5m raise' was published by the Australian Financial Review at 11:38am (AEST) on the same day, which contained details of the capital raising.

The ASX said that Imricor announced the $17.5 million placement and share plan on September 8, and asked how the information in the announcement appeared in the article and what arrangements it had to ensure compliance with Listing Rule 15.7, prohibiting the provision of information to any party prior to the ASX.

In its reply, Imricor told the ASX that it had "no knowledge about how the information regarding its capital raise appeared in the AFR article nor where the information in the AFR article was sourced".

The company said it did not disclose the information to the newspaper, nor did it authorize the release of any information to the publication.

Imricor said it was aware that the joint lead managers to the capital raise, MA Moelis Australia Advisory and Bell Potter Securities, began a process of "wall-crossing" with certain institutional and sophisticated investors after the market close on September 6 "in line with industry standards".

"It may be that the information which appeared in the AFR article, was initially disclosed by one of the investors with whom the information was shared in the wall crossing process," the company said.

Imricor said it "had taken reasonable precautions to prevent the premature dissemination of sensitive information, including ensuring that investors who were wall crossed were bound by restrictions on disclosure of confidential information, and placing the company in a trading halt while negotiating and finalizing the capital raising".

The ASX asked if the current arrangements were inadequate or not being enforced, what additional steps did Imricor intend to take to ensure compliance with Listing Rule 15.7?

"The company is confident that the current arrangements are adequate and are being enforced, and will continue [to] prioritize compliance with its continuous disclosure obligations," Imricor said.

Imricor fell two cents or 1.8 percent to $1.11.

STARPHARMA

Starpharma says the US Patent and Trademark Office has granted a composition of matter patent relating to its dendrimer enhanced product (DEP) cabazitaxel.

Starpharma said the patent, titled 'Therapeutic Dendrimer' would protect its intellectual property until 2039 with the potential for a further five-year extension.

The company said the patent built on its suite of existing DEP patents for the product, specifically covering a DEP conjugated to multiple cabazitaxel drug molecules through a particular releasable linker.

Starpharma was up 5.5 cents or 4.2 percent to $1.365 with 862,372 shares traded.

CYNATA THERAPEUTICS

Cynata says the Russian Federation Patent Office has accepted two patent applications covering its Cymerus mesenchymal stem cell technology.
Cynata said the patents, titled 'Pluripotent Stem Cell Assay' and 'Colony Forming Medium and Use Thereof', were expected to be granted in late 2021 and be valid until 2037.
Cynata was up two cents or 3.7 percent to 56.5 cents.

ARGENICA THERAPEUTICS

Argenica says Melbourne peptide manufacturer, Auspep has produced scaled-up batches of its stroke therapeutic ARG-007 for its proposed phase I trial.
Argenica said that the good manufacturing practice ARG-007 had a "purity profile" of 99.9 percent, above the required level for clinical trials.
The company said it would begin safety and toxicology studies in pre-clinical experiments before the human phase I trials.
Argenica said the manufacture was "an important milestone".
The company said that it separately engaged the Beech Island, South Carolina-based US based peptide manufacturer Ambiopharm, which "also achieved process development optimization of the manufacturing of ARG-007 at a purity of 99.3 percent".
Argenica said the GMP grade material was with its clinical research organisation for use in pre-clinical studies for geno-toxicology, final pharmacokinetics, safety and toxicology studies.
Argenica chief executive officer Dr Liz Dallimore said that passing the "scale-up manufacturing milestone and process optimization is incredibly exciting for Argenica, especially at the very high peptide purities generated".
"We have de-risked our reliance on a sole manufacturing partner and achieved high purity product from both manufacturers," Dr Dallimore said.
Argenica was up three cents or 8.8 percent to 37 cents.

SUDA PHARMACEUTICALS

Suda says shareholders will vote to change the name to Arovella Therapeutics and issue 8,000,000 options to managing-director Dr Michael Baker.
Suda said that Dr Baker's options would be exercisable at 7.5 cents each, within four years.
The company said the meeting would vote to ratify and approve the previous issue of shares, approve the employee share option plan and the issue of 2,923,385 options to Baker Young, exercisable at 7.6 cents each within two years.
Suda said the name change reflected the recent acquisition of its natural killer T-cell therapy platform for cancer and it proposed to change its ASX code from SUD to ALA.
The meeting will be held virtually on October 14, 2021, at 10am (AEDT).
Suda fell 0.3 cents or 5.45 percent to 5.2 cents with 1.1 million shares traded.

ADHERIUM

Regal Funds Management says it has reduced its substantial holding in Adherium from 187,196,934 shares (8.79%) to 156,843,906 shares (7.37%).
The company said that on September 10, 2021, it sold 30,353,028 shares for $634,378 or 2.1 cents a share.
Adherium fell 0.1 cents or 5.6 percent to 1.7 cents with 15.7 million shares traded.

ATOMO DIAGNOSTICS

Atomo says it has appointed Deborah Neff as a non-executive director, effective from September 15, 2021.

Atomo said the US-based Ms Neff was currently advising several early-stage companies developing technologies to improve patient care.

The company said Ms Neff was previously Evanostics LLC and Predicant Biosciences chief executive officer and Complete Genomics and Pathwork Diagnostics chief operating officer.

Atomo said Ms Neff was the head of Becton Dickinson Biosciences and a director of Galt Inc, Vortex Biosciences and Biorad Inc.

The company said Ms Neff held a Bachelor of Science from the University of California, Davis.

Atomo was unchanged at 28.5 cents with 2.3 million shares traded.

ADHERIUM

Adherium says chief financial officer Anne Bell has “stepped down by mutual agreement” effective from September 15, 2021.

Adherium said recruitment for a replacement was underway with the chief financial officer position to be based in Melbourne.

CHIMERIC THERAPEUTICS

Chimeric says it has appointed three cell therapy specialists to the company’s cellular immunotherapy scientific advisory board.

Chimeric said it had appointed the Dana-Faber Cancer Institute’s Dr Eric Smith, the Fred Hutchinson Cancer Research Centre’s Dr David Maloney and the University of Chicago’s Dr Michael Bishop to the advisory board.

Chimeric fell 1.5 cents or 4.4 percent to 32.5 cents.