Biotech Daily

Tuesday July 20, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: TELIX UP 5.5%; PATRYS DOWN 8%**

*** CLARITY $92m IPO FOR CANCER RADIO-PHARMACEUTICALS**

*** MACH7 RECEIPTS UP 23% TO $21m**

*** REDHILL COMPLETES OPAGANIB FOR COVID-19 PNEUMONIA TRIAL**

*** ENA STARTS INNA-051 NASAL SPRAY COVID-19 PREVENTION TRIAL**

*** NOVA EYE UNAUDITED REVENUE UP 6% TO $13.5m**

*** CELLMID RECEIPTS DOWN 32% TO $5.6m**

*** OSPREY: DYEVERT CANADA APPROVAL, GE HEALTHCARE DISTRIBUTOR**

*** EMVISION PREPARES COMMERCIAL PORTABLE BRAIN SCANNER**

*** TELIX: ON-TRACK FOR TLX250-CDX FDA BIOLOGICS APPLICATION**

*** CHINA PATENT FOR RECCE R327, R529**

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*** MTP CONNECT APPOINTS DR AMANDA RUTH 'GUEST OF THE CHAIR'**

*** LIFESPOT: SAICH, DAVIES IN; STEDWELL, CANNAVO OUT**

MARKET REPORT

The Australian stock market fell 0.46 percent on Tuesday July 20, 2021, with the ASX200 down 33.8 points to 7,252.2 points. Six of the Biotech Daily Top 40 stocks were up, 27 fell, six traded unchanged and one was untraded.

Telix was the best of the six, up 28 cents or 5.5 percent to $5.35, with 499,307 shares traded. Mesoblast climbed 3.2 percent; with Clinuvel, CSL, Genetic Signatures, Polynovo and Pro Medicus up by one percent or more.

Patrys led the falls, down 0.4 cents or 8.2 percent to 4.5 cents, with 34.5 million shares traded. Next Science shed six percent; Dimerix, LBT, Medical Developments and Optiscan fell more than four percent; Cyclopharm, Imugene, Nova Eye, Oncosil and Osprey were down three percent or more; Cynata, Kazia, Pharmaxis, Prescient, Resonance and Universal Biosensors shed two percent or more; Compumedics, Immutep, Orthocell, Proteomics and Volpara were down one percent or more; with Avita, Cochlear, Nanosonics, Neuren, Opthea, Resmed and Starpharma down by less than one percent.

CLARITY PHARMACEUTICALS

Clarity says it expects to raise $92 million in a fully-underwritten initial public offer at $1.40 a share to develop and commercialize its radio-pharmaceuticals for cancer.
Clarity said the offer would open on August 3 and close on August 10 and it hoped to list on the ASX under the code CU6 on August 25, 2021.
The company's prospectus said that Clarity had an indicative market capitalization of $358.6 million, not including 25,543,912 China Grand options, exercisable at $1.75 each, giving China Grande about 8.3 percent if exercised, but with several vesting conditions including listing on the ASX and completing an agreement.
Clarity executive chair Dr Alan Taylor said in the prospectus the company's SAR technology employed radioisotopes copper-64 for diagnosis and copper-67 for therapy, "with the aim of achieving superior imaging and highly precise and accurate therapy".
Dr Taylor said the company's first clinical product, Sartate began a first-in-human phase I trial in 2015, which showed the technology's ability to target and visualize the cancer of trial patients, which led to a therapeutic trial of Sartate in children with neuro-blastoma.
Dr Taylor said the diagnostic and therapeutic trials "paved the way for the clinical development of two additional products, SAR-Bombesin and SAR-bis-PSMA, for the management and treatment of breast and prostate cancers.
The prospectus said that Dr Colin Biggin was the managing-director and chief executive officer, with directors including former Cochlear chief executive officer Dr Chris Roberts, Dr Thomas Ramdahl, Dr Gillies O'Bryan-Tear and Rosanne Robinson, with Robert Thomas to join the company on listing on the ASX.
The prospectus said the chief scientific officer was Dr Matt Harris, the director of clinical operations was Michelle Parker and the director of operations was Dr Mike Ironside.
The joint lead managers for the offer are Jeffreys and Bell Potter.
Separately, Clarity said it had begun its 'Propeller' trial of 64-Cu SAR-bis-PSMA for prostate cancer at Perth's Genesiscare and Sydney's Nepean Hospital.
Dr Taylor said that 64-Cu SAR-bis-PSMA had a combination of two targeting agents attached to the SAR technology.
"The preclinical data to date is compelling, with both higher tumor uptake and greater tumor retention compared to the single targeted products utilized by other radiopharmaceutical products on the market, and we look forward to recruiting our first patient for this trial shortly".
Clarity said the 30-patient, phase I positron emission tomography (PET) imaging trial of participants with confirmed prostate cancer using 64-Cu-SAR-bis-PSMA was blinded review, dose-ranging, non-randomized study prior to radical prostatectomy.
The company said that the primary endpoints of the trial were safety, tolerability and efficacy in the detection of primary prostate cancer compared to histopathology.
The prospectus is available at: link https://events.miraqle.com/clarity-ipo.
Clarity is a public unlisted company.

MACH7 TECHNOLOGIES

Mach7 says receipts from customers for the year to June 30, 2021 was up 22.85 percent to $21,000,000 compared to the previous corresponding period.
Mach7 said that receipts from customers for its medical imaging products for the three months to June 30, 2021 fell 30.8 percent to $4,546,000.
The company said it had "highest annual sales orders on record" up 95.1 percent to $25.64 million for the year to June 30, 2021.
Mach7 fell 5.5 cents or 5.7 percent to 90.5 cents with 4.1 million shares traded.

REDHILL BIOPHARMA

Redhill says that treatment and follow-up has been completed in its 475-patient, phase II/III study of opaganib for patients hospitalized with severe Covid-19 pneumonia.
Redhill said that top-line results were expected “in the coming weeks”.
Last year, the company began a trial of opaganib for Covid-19 in Israel and Italy, later adding Russia, the UK and other European sites to the trial (BD: Apr 7, Jun 11, 2020).
Today, Redhill said that opaganib was a dual anti-viral and anti-inflammatory investigational Covid-19 pill, which had demonstrated potent inhibition of the beta and gamma variants of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) and was expected to be effective against emerging variants, including delta and delta plus.
In January, Redhill said that the top-line data from its 40 hospitalized patient, phase II study of opaganib for Covid-19 in the US showed that it assisted recovery and was safe (BD: Jan 17, 2021).
Redhill medical director Dr Mark Levitt said that Sars-Cov-2 variants were capable of evading vaccines’ effects.
“Not only does this threaten efforts to control the pandemic, but it also brings into sharp focus the urgent need for effective oral Covid-19 therapies capable of working despite the emergence of variants,” Dr Levitt said.
“This makes the completion of this study even more significant, given its potential to be a game-changer in the treatment of Covid-19,” Dr Levitt said.
Redhill said the trial’s primary endpoint was the proportion of patients breathing room air without oxygen support by day-14, with additional outcomes including time to hospital discharge, improvement, incidence of intubation and mortality.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
On the Nasdaq, Redhill was up 29 US cents or 4.86 percent to $US6.26 ($A8.55) with 720,643 shares traded.

ENA RESPIRATORY

Ena says it has begun a phase I safety study of its INNA-051 nasal spray for the prevention of Covid-19, at Scientia Clinical Research in Sydney.
Ena said the randomized, double-blind, placebo-controlled, single and multiple ascending dose study would assess safety, pharmaco-kinetics and pharmaco-dynamics of the therapy.
The company said that INNA-051 activated the “innate immunity in the nose” the primary entry portal of most respiratory viral infections including Covid-19, influenza and the common cold and reduced Covid-19 replication by up to 96 percent in ferrets.
In June, Brandon Capital said that with the Minderoo Foundation and Uniseed it had raised $32.5 million for Melbourne’s Ena to develop INNA-051 for Sars-Cov-2 and other viruses (BD: Jun 17, 2021).
The company said it was seeking 100 healthy people in Sydney for the phase I trial, which it hoped to complete by the end of September.
Scientia medical director and principal investigator Dr Charlotte Lemech said that despite the current pandemic measures in Sydney “we have put in place additional safety procedures and our trial is continuing”.
“We have dosed a number of cohorts so far and they are tolerating the therapy well,” Dr Lemech said.
Ena is a private company.

NOVA EYE MEDICAL

Nova Eye says unaudited group revenue for the year to June 30, 2021 is up four to six percent to $13.2 million to $13.5 million compared to the prior corresponding period.
Nova Eye said its unaudited sales revenue from its glaucoma surgical devices for the year to June 30, 2021 was expected to be up 13 to 15 percent at $13.1 million to $13.4 million compared to $11.6 million for the year to 30 June 2020.
The company said it expected its overall unaudited loss before interest, taxes, depreciation, and amortization to be between $3.4 million and $3.7 million for the year to June 30, compared to the $5.9 million loss at June 30, 2020.
Nova Eye fell one cent or 3.3 percent to 29 cents.

CELLMID

Cellmid says receipts from customers for the year to June 30, 2021 was down 31.9 percent to $5,613,000 compared to the previous corresponding period.
Cellmid said that receipts from customers for its hair loss products for the three months to June 30, 2021 was down 47.1 percent to $580,000.
The company said it had cash equivalents of $6,728,000 at June 30, 2021 compared to the $6,970,000 at June 30, 2020.
Cellmid was up 0.1 cents or 1.7 percent to six cents.

OSPREY MEDICAL

Osprey says Health Canada has granted a medical device licence for its Dyevert cardiac dye reduction system, with GE Healthcare Canada appointed its distributor.
Osprey said the Dyevert approval followed the “positive scientific evidence that supports its quality, safety and efficacy in reducing contrast induced acute kidney injury.
The company said it had a four-year exclusive agreement with the Mississauga, Ontario-based GE Healthcare to distribute its Dyevert systems in Canada.
Osprey said its Dyevert portfolio reduced the amount of contrast dye used in heart imaging procedures and had been proved to reduce contrast induced acute kidney injury by about 55 percent without compromising image quality.
Osprey fell 0.05 cents or 3.45 percent to 1.4 cents with 2.1 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says the assembly of its first-generation portable brain scanner is on target to be completed “next month”.
Emvision said the device was intended for commercialization to be used in intensive care units, stroke and neurology wards, angiogram suites and emergency departments.
The company said the device was comparable in size to a cart-based ultrasound unit and could be wheeled directly to the patient’s bedside for point-of-care neuro-imaging, to offer bedside decision support and monitoring capability for stroke patients.
Emvision chief executive officer Dr Ron Weinberger said that “despite the Covid-19 restrictions in [New South Wales] we have been able to keep progressing well.”
“Substantial effort has gone into design for manufacture and reducing our bill of materials in line with our commercial objectives,” Dr Weinberger said.
Dr Weinberger said the consumable portfolio had “the potential to contribute an attractive annuity income stream for the company”.
Emvision was unchanged at $2.75.

TELIX PHARMACEUTICALS

Telix says despite pandemic impact on trial recruitment, it is on track to begin its US Food and Drugs Administration biologics licence application by the end of the year.
Telix said its Zircon phase III trial of TLX250-CDx for clear cell renal cancer imaging with positron emission tomography had exceeded 50 percent recruitment of the 252 patients, with sites currently recruiting five to 10 patients per week.
The company said it was recruiting patients at 34 sites in the European Union, Turkey, Australia, US and Canada and it expected to complete recruitment in the next four to five months, subject to ongoing pandemic conditions.
Telix was up 28 cents or 5.5 percent to $5.35 with 499,307 shares traded.

RECCE PHARMACEUTICALS

Recce says the Chinese Patent Office has granted a patent covering its R327 synthetic antibiotic and R529 anti-viral.
Recce said that the patent, titled 'Anti-Virus Agent and Method for Treatment Of Viral Infections', would protect its intellectual property until February 2037.
The company said the patent covered the composition and method of its anti-infectives, use of R327 or R529 for the treatment of viruses having a lipid envelope or coat and administration by oral, injection, inhalation and transdermal dose applications.
Recce said patents had been granted in Europe and Japan, Australia and had application in other countries.
Recce was up 11 cents or 11.5 percent to $1.07 with 1.2 million shares traded.

AUSCANN GROUP HOLDINGS

Auscann says it has begun its application to the Australian Pesticides and Veterinary Medicines Association for its marijuana-based Dermacann for dogs with skin conditions.
Auscann said Dermacann "was shown to be safe and effective at reducing inflammatory skin lesions in dogs diagnosed with atopic dermatitis" in a randomized, placebo-controlled, double-blind study.
The company said dogs treated with Dermacann showed "substantial improvement in canine atopic dermatitis extent and severity index (CADESI-4) scores" with an average reduction of 51 percent compared to a slight increase in the dogs receiving placebo between over 56 days.
Auscann said the safety and toxicology evaluation for the application of its Dermacann for anti-inflammatory and immune support in dogs was led by the company's head of research and development Dr Margaret Curtis and toxicologist Dr Jeffrey Sherman.
Auscann chief executive officer Layton Mills said that starting the registration pathway with the Australian Pesticides and Veterinary Medicines Association was "consistent with Auscann's objective of bringing safe, clinically developed and tested medicines for human and animal health to meet patients' unmet health needs".
Auscann was unchanged at 10.5 cents with 1.7 million shares traded.

INCANNEX HEALTHCARE

Incannex has requested a trading halt "pending an announcement … regarding a material patent update and receipt of ethics approval for research studies".
Trading will resume on July 22, 2021 or on an earlier announcement.
Incannex last traded at 27.5 cents.

CORRECTION: ADALTA

Yesterday's edition incorrectly said Adalta had approval for a phase II efficacy study of inhaled AD-214 for idiopathic pulmonary fibrosis and other interstitial lung diseases.
The Monday sub-editor confused the announcement of ethics approval to move to a higher dose in the phase I trial with planned efficacy studies.
Adalta also announced that it had terminated the phase I trial and would proceed directly to inhaled AD-214 efficacy studies in 2023.
The sub-editor was confused by the large number of words on the page and has been returned to the sub-editors' dungeon to refresh her reading and comprehension skills.
Adalta fell two cents or 14.8 percent to 11.5 cents with 3.4 million shares traded.

COCHLEAR

Cochlear says that non-executive director Abbas Hussain has resigned to "focus on his appointment as the chief executive officer" of Switzerland's Vifor Pharma Group.
Cochlear said Mr Hussain joined the company in 2018 and thanked him for his service.
Cochlear fell 21 cents or 0.1 percent to $241.11 with 104,439 shares traded.

ONCOSIL MEDICAL

Oncosil says it has appointed Otto Buttula as a non-executive director, with Dr Chris Roberts and Michael Bassett retiring at the annual general meeting in October, 2021.
Oncosil said after Dr Roberts' departure, it expected Mr Buttula to be elected as chair.
The company said Mr Buttula had more than 30 years of experience in investment research, funds management and information technology and was formerly the co-founder, chief executive officer and managing director at IWL, and currently a director of Imugene and chair at Rhythm Biosciences and Hitiq.
Oncosil fell 0.2 cents or 3.3 percent to 5.9 cents with 2.7 million shares traded.

MTP CONNECT

MTP Connect says it has selected Rare Cancers Australia head of policy and public affairs Dr Amanda Ruth as its next "guest of the chair".
MTP Connect said the program "provides emerging leaders in the medical technology, biotechnology and pharmaceutical sector with a range of board-level experiences".
The Federally-funded industry organization said that Dr Ruth would attend its board meetings over the next 12 months "to gain new perspectives on how boards operate".
MTP Connect chair Sue MacLeman said the guest of the chair initiative was an example of how organizations could do more to develop board-ready leaders.
"As guest of the chair, Dr Ruth will be exposed to a new level of company management, financial planning and corporate governance and will be involved in our key events throughout the year," Ms MacLeman said.
"These are experiences that emerging leaders would otherwise not be exposed to at this stage of their careers, so by providing these opportunities, we're preparing our future industry leaders and building our sector's capacity and resilience," Ms MacLeman said.
MTP Connect said that Dr Ruth previously worked in market access, health economics, policy and government affairs, for companies including Celgene, Bristol-Myers Squibb, Johnson & Johnson Medical, Eli Lilly and Deloitte Access Economics.
The company said that Dr Ruth held a Doctor of Philosophy in immunology from Monash University.

LIFESPOT HEALTH

Lifespot says Dr Andrew Saich and Darryl Davies will replace non-executive directors Justyn Stedwell and Francesco Cannavo, effective from today.

Lifespot said Dr Saich had extensive experience of international management, commercialization and pharmaceutical research and development and was currently the chief medical officer at Return Health.

Lifespot said Mr Davies had more than 15 years of experience in psychology, healthcare and harm minimization and was the co-founder and chief executive officer of Cannvalate Pty Ltd.

Lifespot was unchanged at 10 cents with 1.4 million shares traded.