Biotech Daily

Wednesday May 24, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PATRYS UP 10%; STARPHARMA DOWN 9%**

*** IP GROUP $2.25m TO RESSEPTOR FOR AUTOIMMUNE DISEASES, CANCER**

*** BRANDON CUREATOR $1.5m FOR QIMR CYTEPH FOR GLIOBLASTOMA**

*** BRANDON CUREATOR $500k FOR CENTENARY POMPE AAV GENE THERAPY**

*** IMMUTEP EFTI NSCLC INSIGHT-003 TRIPLE COMBINATION 'PROMISING'**

*** PHARMAXIS: 'PXS-6302 REDUCES COLLAGEN 30%, NOT SCARS'**

*** RESPIRI NOTES RAISE $4.5m, $2m PLAN FOR ACCESS MANAGED SERVICES**

*** RESPIRI TAKES WHEEZO TO US, QUITS AUSTRALIA**

*** ACTINOGEN AMENDS, DELAYS XANAMEM ALZHEIMER'S TRIAL**

*** CLARITY INCREASES COPPER-67 PROSTATE CANCER DOSE**

*** TGA, NZ MEDSAFE APPROVE BTC ELASTOQ INFUSION PUMP**

*** RHYTHM APPOINTS LINK UK COLOSTAT DISTRIBUTOR**

*** PATRYS: PAT-DX1 'NO TOXICITY IN RATS, PRIMATES'**

*** LAZARD BELOW 5% IN MAYNE PHARMA**

*** BREATHE TAKES 32.3% OF BIOXYNE; CUSTODIAN, VIG BELOW 5%**

*** RESPIRI APPOINTS BRIAN LEEDMAN DIRECTOR**

*** ONCOSIL TO LOSE CHAIR OTTO BUTTULA; CFO, CO SEC KARL PECHMANN**

MARKET REPORT

The Australian stock market fell 0.64 percent on Wednesday May 24, 2023, with the ASX200 down 46.1 points to 7,213.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell, four traded unchanged and two were untraded. All three Big Caps fell.

Patrys was the best, up 0.1 cents or 10 percent to 1.1 cents, with 6.8 million shares traded. Immutep and Oncosil climbed more than seven percent; Atomo, Cynata, Genetic Signatures and Impedimed improved more than three percent; Clinuvel, Cyclopharm and Polynovo rose more than two percent; with Dimerix, Micro-X, Opthea and Paradigm up by more than one percent.

Starpharma led the falls, down four cents or 9.3 percent to 39 cents, with 442,706 shares traded. Pharmaxis lost 9.1 percent; Actinogen shed 8.6 percent; Medical Developments was down 5.1 percent; Antisense, Imugene, Mesoblast, Neuren, Universal Biosensors and Volpara fell more than four percent; Proteomics was down 3.65 percent; Amplia, Avita, Kazia, Nanosonics, Next Science and Telix shed more than two percent; CSL, Emvision, Prescient and Pro Medicus were down more than one percent; with Cochlear and Resmed down by less than one percent.

IP GROUP AUSTRALIA, RESSEPTOR THERAPEUTICS

Melbourne's Resseptor says it has $2.25 million from a funding round led by IP Group Australia to develop therapies for autoimmune diseases and cancer.
In 2017, London's IP Group PLC said had at least $200 million for developing spin-out companies from nine Australia and New Zealand universities.
(BD: May 30, 2017).
Today, a joint media release from Resseptor and the IP Group said that Resseptor hoped to develop therapies for inflammatory conditions based on technology that improved how the immune system recognized and responded to tissues, malignancy and pathogens.
The IP Group said that the discoveries were made by researchers at Monash University, with the core intellectual property licenced to Resseptor by Monash Innovation.
The IP Group said that the founding team was based at Monash University, La Trobe University and the Queensland University of Technology.
Monash Innovation commercialization director Dr Katherine Nielsen said that Resseptor was "an example of the translation of impactful inventions emerging from Monash researchers tackling the great challenges in treating inflammatory diseases, an area of expertise in the Faculty of Medicine, Nursing and Health Sciences".
"Our partnership with IP Group has been long-standing, and this seed funding for Resseptor marks the sixth investment in a Monash University spinout," Dr Nielsen said.
Resseptor is a private company.

QUEENSLAND INSTITUTE OF MEDICAL RESEARCH BERGHOFER, CYTEPH

The Queensland Institute of Medical Research says spin-out Cyteph has been awarded $1.5 million for glioblastoma from Brandon Biocatalyst incubator Cureator.
The Institute said that the grant launched Cyteph to conduct a phase I trial of CYT-101 for recurrent glioblastoma multiforme.
QIMR said that Cyteph hoped to develop allogeneic or off-the-shelf T-cell therapies and a dual-targeting chimeric antigen receptor T-cell (Car-T) platform to treat solid tumors.
The Institute said that CYT-101 was an allogeneic cyto-megalo-virus (CMV)-specific T-cell therapy developed by Prof Rajiv Khanna and his team, and the immune-therapy used the immune system and virus-specific T-cells to recognize and attack cancer cells.
QIMR said that cyto-megalo-virus-specific T-cells were effective at targeting and destroying virus-infected and malignant cells because they were "primed in the body as killer T-cells which rapidly migrate and penetrate deep into diseased tissues".
The Institute said the program had been de-risked through two previous clinical trials using autologous cyto-megalo-virus-specific T-cell therapy in glioblastoma multiforme patients, where it was found to be safe with preliminary efficacy signals.
QIMR said that autologous treatments using the patient's own immune cells were costly, could take many weeks, and the immune cells could be dysfunctional, but allogeneic, or off-the-shelf, treatments used donor cells from healthy volunteers, with a "more robust and consistent product with longer duration and treatment without delay".
The Institute said that Cyteph planned to use allogenic cyto-megalo-virus-specific T cells as a dual targeting, Car-T delivery platform for solid tumors.
QIMR said the first Car-T asset in pre-clinical development using the platform, CYT-AT1, targeted EphA3 positive solid tumors such as glioblastoma multiforme, colorectal, prostate and lung cancer.
Cyteph is a private company.

CENTENARY INSTITUTE, BRANDON CAPITAL

The Centenary Institute says that with the Sydney Local Health District it has been awarded $500,000 for gene therapy from the Brandon Biocatalyst incubator Cureator.
The Centenary Institute said the gene therapy would be developed by researchers at Aavec Bio working on adeno-associated virus (AAV) technology, with the first indication Pompe disease.
The Institute said the “bio-engineered virus technology … serves as a vehicle to transport healthy genes to cells … [and would be used] to potentially cure a diverse group of genetic diseases”.
The Centenary Institute said the research team, led by Prof John Rasko hoped to develop an adeno-associated virus that would be more effective at delivering therapeutic genes to the correct cells in the body.
The Institute said there were limitations with of adeno-associated virus-based gene therapy, including the need for high doses to achieve therapeutic effects, dose-related toxicities and high manufacturing costs.
“The success of gene therapy depends on how effectively the therapeutic payload is delivered to target cells in the body,” Prof Rasko said.
“Our novel platform could greatly improve human gene therapies, leading to more effective treatments for those suffering with unmet medical needs.
It would also mean substantially reduced dosage levels are required, with less toxicities and side effects, leading to improved outcomes for patients,” Prof Rasko said.
Prof Rasko said the Centenary project could decrease manufacturing costs, due to the reduced amount of therapeutic material required.
“This cost saving could potentially transform the gene therapy market by making these treatments far more accessible and affordable to patients,” Prof Rasko said.
The Centenary Institute said that the first indication would be Pompe disease, which led to progressive muscle weakness and cardiac damage.
The Institute said that Pompe disease affected the body’s ability to breakdown glycogen, which accumulated in tissues including muscle and affected about one-in- 40,000 people globally.

IMMUTEP

Immutep says its efti triple combination therapy trial for first line non-small cell lung cancer (NSCLC) shows it is well tolerated and has “promising initial signals of efficacy”.
Earlier this year, Immutep said it had enrolled all 20 patients in its trial of eftilagimod alpha, or efti and formerly IMP321, with standard-of-care anti-programmed cell death protein-1 (anti-PD-1) therapy and chemotherapy using carboplatin and/or pemetrexed for non-small cell lung cancer (BD: Feb 6, 2023).
Today, the company said the investigator led trial at the Frankfurt Institute of Clinical Cancer Research showed the triple combination of efti with anti-PD-1 and chemotherapy had an overall response in 14 of the 21 patients (67%) and disease control in 19 of the 21 patients (91%).
Immutep said that 17 of the 21 patients (81%) had a programmed death ligand-1 (PD-L1) tumor proportion score of less than 50 percent, who were less responsive to anti-PD-1 based therapy compared with PD-L1 high expressing patients.
Immutep chief scientific officer Dr Frédéric Triebel said the company had made significant progress with its later-stage development planning to treat one of the most common cancer indications.
Immutep was up 2.5 cents or 7.6 percent to 35.5 cents with 3.4 million shares traded.

PHARMAXIS

Pharmaxis says its 42-patient, phase Ic trial shows that PXS-6302 topical cream reduces collagen in scars by 30 percent but not the appearance of scars at three months.

The company said that the lack of improvement in scar appearance at three months "points to [a] need for [a] longer study in established scars".

Earlier this year, Pharmaxis said that it had dosed its first of 50 patients in a 12-week, placebo-controlled, phase Ic, safety and tolerability trial of PXS-6302 for scar reduction (BD: Jan 31, 2022).

The company said that the trial was led by Prof Fiona Wood at the University of Western Australia and met its primary endpoint of safety and tolerability with PXS-6302 "very well tolerated and demonstrated a good safety profile" with no serious adverse events reported.

Pharmaxis said that "two patients withdrew from the study after reporting redness and itching at the site of application which resolved after treatment was stopped".

The company said that PXS-6302 cream was applied three times a week and resulted in a mean 66 percent reduction in lysyl oxidase enzyme (LOX) activity when measured two days after the last dose compared to baseline and the placebo group ($p < 0.001$).

Pharmaxis said that lysyl oxidase enzyme was responsible for the cross-linking of collagen fibres implicated in adverse scarring.

The company said that patients had "a wide variety of scar types of generally low to moderate severity and with an average scar age of 12.8 years".

Pharmaxis said that patients and clinicians qualitatively evaluated a number of different aspects of the scar and "no significant differences in the overall score were seen between active and placebo groups after three months of treatment".

Prof Wood said that the study "significantly enhanced our understanding of the role of LOX enzymes in scarring and the scar process itself".

"PXS-6302 safely inhibits these key enzymes to a significant degree and leads directly to an unprecedented change to the scar composition that we have not seen with any other form of treatment," Prof Wood said.

"We estimate that up to 50 percent of the excess collagen in these patients' scars has been removed," Prof Wood said.

"While the length of this phase Ic safety study was not sufficient to change the appearance of an established scar, the re-modelling process will be ongoing and I'm confident we would see an improvement in scar appearance and physical characteristics if we observed them for longer," Prof Wood said.

"The collected data also bodes well for studying the effect of LOX inhibition on the prevention of scars after surgery and in younger scars where the re-modelling process is more aggressive and probably more sensitive to intervention with a LOX inhibitor," Prof Wood said.

Pharmaxis chief executive officer Gary Phillips said that the pre-clinical work conducted by Prof Wood's team "clearly pointed to the significant role played by LOX enzymes in skin scarring".

"This first-in-man clinical study has underlined those findings and pointed the way for future clinical research for our pan-LOX inhibitor," Mr Phillips said.

"I am pleased to announce an extension of our collaboration with Prof Wood and her team at the University of Western Australia," Mr Phillips said.

Pharmaxis fell half a cent or 9.1 percent to five cents with five million shares traded.

RESPIRI

Respiri says will raise $4.5 million in convertible notes to buy distributor Access Managed Services LLC and raise a further $2 million in a share plan at 3.4 cents a share.
Last year, Respiri said it had a five-year, distribution and marketing agreement with the Coral Springs, Florida-based Access Managed Services (BD: Feb 7, 2022)
Today, the company said that Access was a remote patient monitoring and chronic care management services provider and existing sales/ marketing partner for Wheezo, and the binding purchase agreement was for $US3 million ($A4.54 million).
The company said it had an agreement with Obsidian Global Partners LLC to issue $4.5 million in convertible notes in two tranches, pending shareholder approval.
Respiri said the notes had a face value of $US1.15 and a conversion price of a 30 percent premium to the 5-day volume weighted average price to the execution of the first tranche.
Respiri said it would raise about $2 million in a share plan, with one attaching option for every two shares purchased, exercisable at 6.5 cents each by June 30, 2025.
The company said the share purchase plan had a record date of May 19, 2023, would open on May 30 and close on June 20, 2023.
Respir said Evolution Capital was the lead manager to place the notes and shortfall.
Respiri was up 0.1 cents or 2.6 percent to 3.9 cents.

RESPIRI

Respiri says that “in light of Respiri's continued push into the US … [it] has determined to voluntarily recall its Wheezo asthma monitor from the Australian market.
Respiri said it would cancel its registration on the Australian Therapeutic Goods Administration and it was in its best interests “to remove any remaining overheads and resources related to the Australia market and continue its focus on scaling US operations”.
The company said it was working with its Australian distributors and resellers to cease the distribution and sale of the Wheezo and had an in-principle plan with distributor Cipla Australia Pty Ltd to cease distribution and recall remaining product.
Respiri managing-director Marjan Mikel said the decision to exit the non-reimbursed Australia and redeploy resources was “obvious for Respiri as we continue to accelerate the scaling of our newly acquired Access [remote patient monitoring] business in the US”.
“Further, this will not incur any significant costs and the repurposing of returned Wheezo devices is opportune as it helps meet the projected US demand,” Mr Mikel said.

ACTINOGEN MEDICAL

Actinogen says it has amended its 330-patient phase IIb trial of Xanamem for Alzheimer’s disease and expects a delay of up to 12 months.
Last year, Actinogen said the US Food and Drug Administration had agreed to the six-month trial of 5mg and 10mg Xanamem for early-stage Alzheimer’s disease to begin in July 2023, with results expected in 2024 (BD: Dec 22, 2022).
Today, the company said the changes included a new tablet formulation and an extended treatment period of 36-weeks to improve the assessment of disease-modification effects.
Actinogen said it planned an interim analysis in the middle of trial enrolment, the enrolment of moderate Alzheimer’s patients to match the phase IIa population more closely and a primary endpoint of a composite of several cognitive tests.
The company said that it expected FDA approval of the protocol changes “shortly”, with results by the end of 2025.
Actinogen fell half a cent or 8.6 percent to 5.3 cents with 1.7 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has treated the first six-patient cohort in its phase I/IIa trial of its copper-67 radioisotope therapy for prostate cancer and will increase the dose in cohort 2.

Clarity said no dose limiting toxicities had been reported from the first cohort which received 4.0 gigabecquerels (GBq) of its copper-67 Sar-BIS-PSMA, and that the second cohort would receive an 8.0GBq dose.

Last year, the company said it has treated the first of up to 30 patients in its 'Secure' phase II trial of 67-copper sarcophagine-BIS- prostate-specific membrane antigen (Cu-67-Sar-BIS-PSMA) for prostate cancer at the GU Research Network's Urology Cancer Center in Omaha, Nebraska (BD: Oct 7, 2022).

Today, Clarity said its copper-67 isotope connected two prostate-specific membrane antigen binding motifs to its sarcophagene technology that held the copper isotopes inside a cage-like structure called a chelator, which prevents copper leakage into the body.

Clarity was up 7.5 cents or 11.0 percent to 75.5 cents.

BTC HEALTH

BTC Health says it has marketing approval from the Australian Therapeutic Goods Administration and New Zealand's Medsafe for its Elastoq infusion pump system.

BTC said that Elastoq was a class IIb, single-use device for the continuous and/ or bolus administration of analgesic medicines for intra-operative and post-operative pain management, and chemotherapy medications.

In April, the company said that Avanos Medical would discontinue supply of its acute pain infusion products to Australia and New Zealand from the middle of October 2023, and Avanos product sales totaled $6.7 million or about 80 percent of subsidiary BTC Speciality Health's revenue in the year to June 30, 2022 (BD: Apr 17, 2023).

Today, BTC executive chair Dr Richard Treagus said with its strong position in acute pain management and existing hospital relationships, the company had "moved quickly to establish alternative sources of supply for quality infusion pumps and related consumables".

"Elastoq is the first in a much wider range of infusion pumps, which we expect to make available to hospitals over the coming months," Dr Treagus said.

BTC Health was unchanged at two cents.

RHYTHM BIOSCIENCES

Rhythm says it that London's Link Medical Solutions Ltd to market and distribute its Colostat bowel cancer blood test in the UK.

Last week, Rhythm said it has been granted UK Conformity Assessment (UKCA) mark certification for its Colostat blood test for colorectal cancer (BD: May 17, 2023).

Today, Rhythm chief commercial officer Elena Deak said Link's extensive experience in commercializing medical technologies would give the company a UK footprint and help it deliver on its goal in making Colostat available in multiple markets.

The company did not disclose the material terms of the agreement.

Rhythm fell 2.5 cents or 5.6 percent to 42.5 cents with 3.0 million shares traded.

PATRYS

Patrys says rat and non-human primate toxicology studies of its humanized deoxymab antibody PAT-DX1 for cancer have found no safety or tolerability issues.
Earlier this year, the company said its phase I trial of PAT-DX1 for cancerous tumors had been delayed to 2024 due to sporadic issues relating to the cell line used to produce the drug (BD: Mar 31, 2023).
At that time, Patrys managing-director Dr James Campbell said the remaining, non-clinical toxicology study of the drug was scheduled to be in May.
Today, Patrys said that none of the results were likely to impact the company's ability to begin human clinical studies of PAT-DX1.
"These studies are expected to complete the regulatory safety requirements that need to be fulfilled in order to start a clinical trial in cancer patients," Dr Campbell said.
"In the meantime, we believe that we will be able to restart manufacturing for the PAT-DX1 material for the clinical trial … [by October] 2023," Dr Campbell said.
Patrys was up 0.1 cents or 10 percent to 1.1 cents with 6.8 million shares traded.

MAYNE PHARMA GROUP

Lazard Asset Management Pacific says it has ceased its substantial shareholding in Mayne Pharma.
The Sydney-based Lazard said that between March 22 and May 19, 2023 it bought and sold shares and a range of prices, with the single largest sale 686,536 shares on May 19 for $2,556,433, or $3.72 a share.
Mayne Pharma fell 13 cents or 3.5 percent to $3.60.

BIOXYNE

Bioxyne says it is substantial in itself, Breathe International has become substantial and Custodian Nominee Company Ltd and VIG Ltd have been diluted below substantial.
In three separate substantial shareholder notices, Bioxyne said it had become substantial in itself with 1,230,000,000 shares (64.89%) and the London-based Breathe International Ltd said it had become substantial with 614,001,384 shares (32.29%).
Earlier this week, the company said it had completed the acquisition of 83 percent of Breathe Life Sciences, issuing 1,230,000,000 shares to shareholders, 576,268,527 shares to Breathe International and up-to 37,732,857 shares to subsidiary Zonetech Wellness (BD: May 22, 2023).
Today, the Auckland, New Zealand-based Michael Sorenson said Custodian Nominee Company's holding of 34,836,169 shares and VIG's holding of 80,652,003 shares were diluted below five percent in Bioxyne.
Bioxyne fell 0.3 cents or 13.0 percent to two cents.

RESPIRI

Respiri says it has appointed Brian Leedman as a non-executive director of the company.
Resipri said Mr Leedman was currently a director of Oncosil and was previously a founder of Resapp Health and a director of Biolife Sciences, as well as a director of Alcidion and chair of Neurotech, Nutritional Growth Solutions, Neuroscientific Biopharmaceuticals and Ausbiotech Western Australia.
The company said Mr Leedman held a Bachelor of Economics and a Master of Business Administration from the University of Western Australia.

ONCOSIL MEDICAL

Oncosil says non-executive chair Otto Buttula will retire at its annual general meeting and chief financial officer and company secretary Karl Pechmann resigned, today.

Oncosil said if mutually agreed Mr Buttula would retire “once either board renewal and an adequate handover [occurred], or a potential takeover can be completed”.

Mr Buttula said the company remained “in discussions with its advisers regarding attracting a new cornerstone shareholder, or full takeover”.

The company said Mr Pechmann had resigned “to take on the [chief financial officer] role at another ASX listed company”.

“Due to streamlining of the operating structure the roles of chief financial officer and company secretary would be transitioned to The CFO Solution,” Oncosil said.

“I would like to acknowledge Karl for his outstanding commitment and dedication to the company,” Mr Buttula said.

“During his time, he has delivered high quality financial reporting to the market and investors, assisting the board with all matters financial, corporate governance and regulatory together with strong finance and operational business leadership,” Mr Buttula said.

“The board and I wish Karl all the very best in his new role,” Mr Buttula said.

Oncosil was up 0.1 cents or 7.7 percent to 1.4 cents with 16.4 million shares traded.