Biotech Daily

Monday September 26, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 6%; UNIVERSAL BIO DOWN 13.5%**

*** PHARMAXIS: PXS-6302 'INHIBITS ENZYMES IMPLICATED IN SCARING'**

*** PARADIGM: BRAZIL PPS FOR MPS TRIAL 'NO ADVERSE EVENTS'**

*** JAPAN GOVERNMENT PROGRAM EXPANDS PAINCHEK MARKET**

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*** EMYRIA: 8 SITES FOR PHASE III MARIJUANA EMD-RX5 DISTRESS TRIAL**

*** ONCOSIL 20m DIRECTORS OPTIONS, 2.5m M-D RIGHTS AGM**

*** EMYRIA 3m OPTIONS FOR M-D DR MICHAEL WINLO AGM**

*** MEDICAL DEVELOPMENTS 2nd STRIKE BOARD SPILL AGM**

*** MEDICAL DEVELOPMENTS TO LOSE DIRECTOR MAX JOHNSTON**

MARKET REPORT

The Australian stock market fell 1.6 percent on Monday September 26, 2022, with the ASX200 down 105.3 points to 6,469.4 points. Ten Biotech Daily Top 40 companies were up, 24 fell, three traded unchanged and three were untraded. All three Big Caps rose.

Oncosil was the best, up 0.3 cents or 6.25 percent to 5.1 cents, with 245,505 shares traded. Nanosonics climbed 4.7 percent; Next Science was up 3.5 percent; Cochlear, CSL, Micro-X, Pharmaxis, Resmed and Telix rose more than two percent; Actinogen and Atomo were up more than one percent; with Mesoblast and Pro Medicus up by less than one percent.

Universal Biosensors led the falls, down 3.5 cents or 13.5 percent to 22.5 cents, with 523,716 shares traded; followed by Resonance down 12.7 percent to 5.5 cents, with 309,759 shares traded. Alcidion lost 11.1 percent; Kazia and Starpharma fell more than seven percent; Cyclopharm shed 6.1 percent; Clinuvel, Imugene and Neuren were down five percent or more; Avita, Genetic Signatures, Medical Developments, Patrys and Volpara fell four percent or more; Dimerix, Emvision and Proteomics lost more than three percent; Compumedics, Orthocell, Paradigm and Prescient shed two percent or more; Antisense and Opthea fell more than one percent; with Polynovo down 0.4 percent.

PHARMAXIS

Pharmaxis says early data from a trial of topical PXS-6302 shows “a high level of inhibition of enzymes and changes in biomarkers that are implicated in scaring”.

Pharmaxis said the interim results from skin-punch biopsies of eight of the planned 50-patients showed skin penetration and high inhibition of the lysyl oxidase enzymes fundamental to the scarring process; reduction in scarring biomarkers suggesting a normalization of physiological processes and a disease modifying effect; with four patients withdrawing from the study after experiencing redness and itching at the site of application that resolved on treatment cessation.

Earlier this year, the company said that the phase Ic, 12-week, placebo-controlled, safety and tolerability trial of PXS-6302 for scar reduction trial would be split into two cohorts, with the first of eight adult patients who had scars between one and five-years duration, and the second containing 42 patients being split equally between active treatment and placebo (BD: Jan 31, 2022).

Today, Pharmaxis said that 24 of the planned 42 patients have been recruited in the second cohort of the study, and that “in response to the adverse skin reaction seen with some patients in the unblinded active phase, the treatment regimen has been reduced from once daily to three times a week application”.

The company said that final results were expected by July 2023.

Lead investigator Prof Fiona Wood said the “positive changes in appearance and pliability of scars in those patients on active drug … need to be confirmed by the results from the placebo-controlled phase of this trial later this year”.

“We are learning a lot as we move from the promising pre-clinical work done at [University of Western Australia] and into the clinic where we have many patients who are in great need of a treatment that can improve both the cosmetic appearance of their scars and improve the functionality of their scarred skin; factors that have a huge impact on patient’s wellbeing,” Prof Wood said.

Pharmaxis was up 0.2 cents or 2.4 percent to 8.4 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says there were “no serious adverse events” in its 12-patient, phase II trial of injectable pentosan polysulfate sodium (PPS) for muco-poly-saccharidosis type VI.

Last year, Paradigm said its Brazil-based, randomized, double-blind, placebo-controlled trial would evaluate the safety and tolerability of PPS for patients aged nine to 16 years with muco-poly-saccharidosis type VI (MPS VI) who had pain and functional deficiency due to disease-related musculo-skeletal symptoms (BD: Jun 18, 2021).

The company said that eight patients would receive PPS while four would receive placebo, all subjects would be provided enzyme replacement therapy throughout the trial, and subjects would have weekly sub-cutaneous PPS at 1.5mg/kg for nine years or above or 1.0mg/kg for subjects below the age of nine years, or placebo, for 24 weeks.

At that time, Paradigm said the muco-poly-saccharidosis type VI was an orphan disease and classified as a rare autosomal recessive, inherited lysosomal storage disorder caused by a deficiency of N-acetyl galactosamine 4–sulfatase.

Today the company said the safety review was a “key milestone” and allowed for the inclusion of subjects aged five to nine to assess the safety and tolerability of PPS.

Paradigm chief executive officer Marco Polizzi said “the ability to include the youngest patient cohort following a positive safety review is important for the commercial potential of PPS to treat the residual symptoms that impact the daily activities of MPS sufferers”.

Paradigm fell three cents or 2.4 percent to $1.24.

PAINCHEK

Painchek says it will expand its pain assessment technologies into Japan after being accepted into a Japan Government’s business connect program for 2022.

Painchek said that the Jetro program was “Japan’s core governmental organization for promoting inward foreign business” and it would receive “comprehensive support services to enter Japan” including market data, online business matching events and regulatory clearance guidance.

The company said Japan had one of the oldest populations and was an “excellent opportunity” for Painchek.

Painchek chief executive officer Philip Daffas said “a priority for Jetro was identifying companies for the program that had developed new digital healthcare technologies, with image diagnosis a specific focus point”.

“This made Painchek an outstanding candidate for Jetro,” Mr Daffas said.

“This new initiative combined with our recent contact with [US Food and Drug Administration] means Painchek can now plan effectively for market entry into the US and Japan - two of the world’s largest medical device and aged care markets,” Mr Daffas said.

Painchek fell 0.1 cents or 3.2 percent to three cents with 2.4 million shares traded.

OPTHEA

Opthea says it has raised $940,497 of a hoped for $5 million in its non-underwritten share purchase plan at $1.15 a share, taking the total raised to $129.5 million.

Last month, Opthea said it expected to raise $US263.5 million ($A370.6 million) through a $US170 million ‘non-dilutive’ facility with Launch Therapeutics, a $US90 million ($A128.57 million) placement, and a $5 million share plan (BD: Aug 15, 2022).

At that time, the company said the $1.15 a share price was a 12.6 percent discount to the 10-day volume-weighted average price to August 10.

Opthea fell 1.5 cents or 1.3 percent to $1.12.

MEDLAB CLINICAL

Medlab says it has received $3,588,112 from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program.
Medlab fell nine cents or 0.8 percent to $11.40.

ACRUX

Acrux says it has received $983,422 from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program.
Acrux said the rebate related to expenditure for the year to June 30, 2022.
The company said it expected an additional research and development rebate in the near term for a subsidiary company, and that Ausindustry had favorably assessed its application for a finding that related to overseas activities.
Acrux fell 0.3 cents or 4.8 percent to six cents.

CYNATA THERAPEUTICS, ST VINCENT'S INSTITUTE OF MEDICAL RESEARCH

Cynata and St Vincent's Institute of Medical Research say they have a Federal $958,504 grant to investigate Cymerus mesenchymal stem cells for ischaemic heart disease.
In a joint media release, Cynata and Melbourne's St Vincent's Institute said the grant from the National Health and Medical Research Council was under the Medical Research Future Fund Cardiovascular Health Mission, would "fund a major pre-clinical research project" to be led by St Vincent's Institute's Dr Shiang (Max) Lim.
The media release said that the study would involve the University of Adelaide, the Baker Heart and Diabetes Institute, the University of South Australia, Duke-National University of Singapore Medical School, the University of Arizona, Melbourne's Monash University, Sydney's Westmead Institute for Medical Research, and the Hearts For Heart, which describes itself as a "health promotion charity".
Cynata said it would supply its Cymerus mesenchymal stem cells at its cost to facilitate the study, which was expected to run for two years.
The company said the project would encapsulate the stem cells "in a clinical-grade device which can be implanted below the skin … to allow sustained delivery of the bioactive molecules released by the [stem cells]".
The media release said that the project aimed to optimize the encapsulation approach, and demonstrate long-term cardiac repair in rat and sheep models of acute myocardial infarction, or heart attack.
Cynata and the St Vincent's Institute said that if successful, the studies would support progress to human trials.
Dr Lim said there was an "urgent need for novel therapies to prevent the onset of heart failure and improve survival in patients with [ischaemic heart disease]".
Dr Lim said that St Vincent's Institute "firmly believe that [mesenchymal stem cell] therapy has great potential to address this unmet need".
Dr Lim said that unlike conventional stem cell production methods, which had scale-up and consistency challenges, the Cymerus induced pluripotent stem cell-based approach could provide "an effectively unlimited source of consistent [stem cells]".
"This project aims to accelerate the development of a new, safe and minimally invasive method to deliver the beneficial secretions of Cymerus [mesenchymal stem cells] to patients, using a retrievable encapsulation device that protects the cells, to allow long-term treatment for effective cardiac repair," Dr Lim said.
Cynata was unchanged at 31 cents.

MICRO-X

Micro-X says the US Department of Homeland Security will pay $US440,000 ($A674,361) to extend its development contract for its miniature baggage scanner.

Last year, Micro-X said it had US Government contracts worth up to $US4.1 million for its baggage screening scanner and self-screening portal (BD: Sep 29, 2021).

Today, the company said that the Department of Homeland Security (DHS) would pay an additional $US440,000 to develop a second functioning prototype of its computed tomography baggage scanner by "early 2023".

Micro-X said that the two baggage scanner prototypes would be tested for their ability to detect potential threats, and that the two prototypes would "enable faster and more thorough testing of the unique and disruptive Micro-X design".

The company said that the DHS had "formally executed the optional second phase of the passenger self-screening checkpoint contract" worth $US1.18 million which included the detailed design of a prototype self-screening module.

The company said that the self-screening checkpoint contract of $US2.5 million was divided into an initial one-year concept design phase, worth $US1.31 million, and a second unfunded phase of $US1.18 million for an additional eight months of work, which was conditional on it developing a "realistic and achievable design concept".

Micro-X said its initial design was accepted in June 2022, and that it would continue to work with its existing subcontractors including Monash University, Elenium Automation and Voxel Radar, as well as DHS Transport Security Administration stakeholders.

Micro-X's US subsidiary Micro-X Inc chief executive officer Dr Brian Gonzales said "the close working relationship we have built with the DHS is testament to our technological advances and focus on the passenger and the operators' checkpoint screening".

"We are very pleased with DHS adding a second prototype and exercising the option to design a prototype self-screening module," Dr Gonzales said.

"This is a strong indication of the success of the projects to-date, and it is our goal to continue building on this success toward our vision of building a passenger-focused checkpoint, based on our unique x-ray technology," Dr Gonzales said.

Micro-X was up half a cent or 2.9 percent to 17.5 cents.

RHINOMED

Rhinomed says a 53-child study has shown that Rhinoswab Junior Covid-19 nasal swab is "the preferred method of sample collection for respiratory diseases for children".

Rhinomed said that the study, titled 'Less invasive sars-cov-2 testing for children: A comparison of saliva and a novel Anterior Nasal Swab', was conducted by Melbourne's Murdoch Children's Research Institute and compared the current standard-of-care combined nose and throat swabs to its Rhinoswab Junior nasal swab.

The company said that study showed that the Junior nasal swab was preferred by 88 percent of children when compared with the combined nose and throat swab.

Rhinomed chief executive officer Michael Johnson said with severe-acute-respiratory-syndrome-coronavirus-2 variants continuing to evolve "we need more accurate, consistent and comfortable sample collection methods to encourage people, especially children and vulnerable populations, to keep getting tested".

"The new Murdoch Children's Research Institute study confirms that Rhinoswab Junior is the preferred sampling method," Mr Johnson said. "Rhinomed is proud to have developed a swab that not only works better, but removes anxiety and distress, not just for the children but for their parents and health care workers," Mr Johnson said.

Rhinomed was unchanged at 16 cents.

ALTERITY THERAPEUTICS

Alterity says a 12-participant study shows wearable sensors can help diagnose motor impairment related to disease progression in early multiple system atrophy.

Alterity said a poster from the ongoing 'Biomarkers of Progression in Multiple System Atrophy (Biomuse) study presented at the International Congress of Parkinson's Disease and Movement Disorders, correlated data from wearable sensors with assessments of motor function in individuals with the Parkinson's disease-related multiple system atrophy.

The company said the study showed the sensors provided a quantitative measurement of multiple system atrophy progression not captured by neurological examination.

Alterity managing-director Dr David Stamler said the company was "very encouraged by these findings as they validate the use of wearable sensors in our ongoing ATH434 phase II clinical trial in [multiple system atrophy]".

"Progressive decline in motor function represents an important source of disability in MSA so it is important to have tools to measure it with precision," Dr Stamler said.

Alterity was unchanged at 1.4 cents with 3.3 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it has filed its new drug application to the US Food and Drug Administration for sofpironium bromide for patients with excessive sweating.

Botanix said that sofpironium bromide was a topical gel with "very high statistical significance" for the treatment of primary axillary hyperhidrosis, the medical condition which caused excessive underarm sweating.

In May, the company said it would pay Miami's Brickell Biotech up to $US17 million ($A24 million), plus royalties for sofpironium bromide gel for excessive underarm sweating, and that in recent studies, it achieved statistical significance in all primary and secondary endpoints and had a favorable safety profile (BD: May 4, 2022).

Botanix executive chair Vince Ippolito said "we are delighted with the achievement of this submission milestone.

Mr Ippolito said sofpironium bromide had been approved in Japan with "very strong early sales" and the company was targeting FDA approval by January 2024.

Botanix was up 0.1 cents or 1.6 percent to 6.3 cents.

VGI HEALTH TECHNOLOGY

VGI says it has ethics approval for a 45-volunteer, US pharmaco-kinetics and exercise study of its delta tocotrienols administered through its transmucosal delivery platform.

VGI said the study would begin next month, be led by scientific adviser Dr Jordan Moon and assess the bioavailability of delta tocotrienols (DT3), measuring exercise performance and muscle power for two doses of NE1-Elite over three weeks, along with lactate, glucose and lipids in the blood, as well as changes in muscle and fat mass.

"We have seen some really exciting results which suggest that Invictus' transmucosal delivery platform can accommodate a far wider range of dosages than we had previously thought was possible," Dr Moon said.

"Now we want to see whether multiple higher doses administered over a period of time will translate to improvements in exercise performance," Dr Moon said.

VGI said that a previous study showed that a single 80mg dose of DT3 "resulted in plasma concentrations which were more than double those achieved with a 40mg dose".

On the National (Newcastle) Stock Exchange, VGI was untraded at three cents.

AROVELLA THERAPEUTICS, IMUGENE

Arovella and Imugene say they will combine Arovella's CAR19-invariant natural killer T-cell ALA-101 with Imugene's Oncarlytics platform to target solid tumors.
Arovella and Imugene said they had a 12-month research agreement, Arovella would fund the pre-clinical studies and both companies would retain the intellectual property rights for their platforms, with any new intellectual property generated to be negotiated.
The companies said that Arovella's ALA-101 contained a chimeric antigen receptor (Car) that targeted tumor cells producing CD19 on their surface, and Imugene's Oncarlytics platform "forces" tumor cells to express the CD19 on their surface.
Arovella and Imugene said that by combining the two treatments, ALA-101 could "seek and destroy the solid tumor cells".
Imugene managing-director Leslie Chong said "our Oncarlytics platform opens up the possibility to treat solid tumors with existing CD19 targeting drugs".
"Solid tumors account for more than 90 percent of cancers diagnosed, and our technology has the potential to change the outcomes for these patients," Ms Chong said.
Arovella was up 0.8 cents or 29.6 percent to 3.5 cents with 13 million shares traded.
Imugene fell one cent or 5.3 percent to 18 cents with 41 million shares traded.

EMYRIA

Emyria says it has eight Australian trial sites for its pivotal phase III trial of marijuana-derived EMD-RX5 for psychological distress.
Last month, Emyria said it had ethics approval for a 300-patient, phase III trial of its "ultra-pure" cannabidiol drug EMD-RX5 for psychological distress (BD: Aug 16, 2022).
At that time, the company said the trial would be a multi-centre, double-blind, randomized, placebo-controlled study to assess the effect of one month of treatment with either 50 milligrams EMD-RX5, 150 milligrams EMD-RX5, or placebo, on the symptoms of psychological distress in adults with chronic pain.
Today, the company said a further four sites had been identified for qualification if required with subsidiary Emerald Clinicals supporting patient recruitment.
Emyria managing-director Dr Michael Winlo said the company had "exceptional demand to participate in our phase III program from clinical sites across Australia".
Emyria was unchanged at 22.5 cents.

ONCOSIL MEDICAL

Oncosil says investors will vote to issue directors 20 million options, and managing-director Nigel Lange up-to 2,469,795 performance rights, subject to milestone hurdles.
Oncosil said its annual general meeting would vote to issue director Otto Buttula 8,000,000 options, with 4,000,000 options each to directors Prof Ricky Sharma, Brian Leedman and Dr Martin Cross, exercisable at 12 cents each within five years, vesting in three years from grant if the director remained with the company.
The company said Mr Lange's performance would vest pending total shareholder return milestones.
Oncosil said the meeting would vote to approve its $4 million placement, as well as 3,000,000 shares to Mr Buttula as part of the shortfall from its rights offer, Dr Cross, Prof Sharma and Mr Leedman, the remuneration report and the 10 percent placement facility.
The meeting will be held at K&L Gates, Level 31, 1 O'Connell Street, Sydney on October 25, 2022 at 12pm (AEDT).
Oncosil was up 0.3 cents or 6.25 percent to 5.1 cents.

EMYRIA

Emyria says its annual general meeting will vote to issue managing-director Dr Michael Winlo 3,000,000 options, exercisable at 37.7 cents within four years.

Emyria said shareholders would vote on an employee securities incentive plan which would raise the maximum number of shares for employees to 35,000,000, as well as potential termination benefits which would see shares vesting even if employees no longer remained with the company.

The company said the meeting would vote to re-elect director Matthew Callahan, approve the 10 percent placement facility and the remuneration report, and its proportional takeover bid approval provisions.

The meeting will be held at D2, 661 Newcastle Street, Leederville, Perth, on October 25, 2022 at 9am (AWST).

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments' annual general meeting may vote on a 'second-strike' board spill, following last year's narrow first strike against the remuneration report.

Last year, the Medical Developments meeting voted 4,654,643 votes (28.96%) against the remuneration report with director Philip Powell resigning (BD: Oct 29, 2021).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.

In its most recent filing Medical Developments said it had 86,305,175 shares on offer, meaning that the votes against the 2021 remuneration report amounted to 5.4 percent of the company, sufficient to request extraordinary general meetings.

Medical Developments said the meeting would vote on the remuneration report, election of directors David Williams and Leon Hoare and the ratification of the prior issue of stock.

The meeting will be held virtually and at Deloitte Touche Tohmatsu, Level 30, 477 Collins Street, Melbourne on October 27, 2022 at 1pm (AEDT).

Medical Developments fell 6.5 cents or four percent to $1.545.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says 10-year director Max Johnston will retire, effective from October 27, 2022.

Medical Developments chair Gordon Naylor said the company wished Mr Johnston "well for the future and thank him for his substantial contribution".

"I would especially like to thank Max for his invaluable support through my transition into the chair role and Brent MacGregor's into the CEO role," Mr Naylor said.

"Max's agreement to step into the interim CEO role was critical for the company and Brent and I will miss the wisdom of his counsel," Mr Naylor said.