Biotech Daily

Wednesday August 10, 2022

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: DIMERIX UP 10%; PARADIGM DOWN 7%**

*** MAYNE ($618m) SELLS METRICS TO CATALENT FOR $679m**

*** IMUGENE STARTS PHASE I CHECKVACC TRIAL 3rd COHORT**

*** POLYNOVO ENROLS 1st NOVOSORB SYNPATH FOOT ULCER PATIENT**

*** PATRYS: PAT-DX1 'SIGNIFICANTLY IMPROVES GLIOMA SURVIVAL', IN MICE**

*** EBR: STUDIES SHOW WISE LEADLESS PACEMAKER 'FEASIBLE'**

*** LBT DEVELOPING APAS PHARMA, APAS MICRO**

*** STARPHARMA DEP-ANTIBODY DRUG CONJUGATES FOR MERCK & CO**

*** TRUSCREEN RELAUNCHES DEVICE IN XINJIANG**

*** AI VISUALIZE APPEALS DISMISSAL OF MACH7 LAWSUIT**

*** MEDLAB NRGBIOTIC EUROPE PATENT FOR DEPRESSION**

*** RYDER TAKES 7.9% OF LUMOS**

*** COTIVITI DILUTED TO 8.6% OF MEDADVISOR**

MARKET REPORT

The Australian stock market fell 0.53 percent on Wednesday August 10, 2022, with the ASX200 down 37.1 points to 6,992.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and four were untraded.

Dimerix was the best, up 1.5 cents or 9.7 percent to 17 cents, with 273,822 shares traded. Imugene climbed 9.3 percent; Patrys was up 8.3 percent; Nova Eye rose 7.7 percent; Universal Biosensors climbed 6.6 percent; Antisense was up 5.7 percent; Atomo and Cynata were up more than three percent; Impedimed, Mesoblast and Starpharma rose more than two percent; Oncosil was up 1.7 percent; with Clinuvel, Emvision, Medical Developments, Opthea and Resmed up by less than one percent.

Paradigm led the falls, down 15.5 cents or 7.2 percent to $1.985, with 810,073 shares traded. Prescient lost 5.7 percent; Genetic Signatures fell 4.7 percent; Actinogen, Avita, Kazia and Orthocell were down more than three percent; both Alcidion and Cochlear shed 2.9 percent; Amplia, CSL, Next Science, Pro Medicus, Proteomics and Volpara were down one percent or more; with Neuren and Telix down by more than one percent.

MAYNE PHARMA

Mayne says the Somerset, New Jersey-based Catalent will pay $US475 million ($A679 million) for its Metrics Contract Services development and manufacturing company.
According to its most recent filing, Mayne had 1,739,815,508 on issue, meaning that at its closing price of 35.5 cents, Mayne had a market capitalization of about $617.6 million.
The company said it would receive about $US445 million ($A636 million) in net proceeds after transaction costs, restructuring costs and closing adjustments.
Mayne Pharma said it acquired the Greenville, North Carolina-based Metrics Contract Services provided drug development and commercial manufacturing services, employing more than 400 people.
In 2012, the company said that it had acquired Metrics for $US105 million ($A101.5 million) through a $A65 million placement and a rights offer at 20 cents a share, and a $US44.5 million debt facility (BD: Oct 4, Nov 15, 2012).
Today, Mayne said that as part of the acquisition deal, Catalent had signed a five-year supply agreement which would assure “continuity of supply of certain products from the Greenville facility”.
Mayne chair Frank Condella said the sale of Metrics was “a key driver of the company’s transformation agenda to reposition Mayne Pharma for growth”.
“This transaction unlocks significant value for Mayne Pharma shareholders and creates a leaner and more focused business with financial flexibility to support its strategic priorities,” Mr Condella said.
Mayne chief executive officer Scott Richards saidteh company would “focus on building its women’s health and dermatology portfolios and the international business which have solid long term growth outlooks”.
“The successful commercialization of Nextstellis and accelerating momentum with the recently launched direct-to-consumer campaign in the US are key areas of focus to drive shareholder value,” Mr Richards said.
“We also continue to evolve our US products go-to-market approach entering into new partnerships and developing alternate value propositions to patients to improve access and affordability,” Mr Richards said.
Mayne Pharma was up 1.5 cents or 4.4 percent to 35.5 cents with 59.1 million shares traded.

IMUGENE

Imugene says it has dosed the first patient in the third cohort of its first-in-human, dose escalation phase I trial of Checkvacc for triple negative breast cancer.
In March, Imugene said the up-to 12 patients, phase I Checkvacc trial had begun dosing a second, higher-dose cohort (BD: Mar 24, 2022).
Today, the company said the purpose of the trial was to evaluate the safety and initial evidence of efficacy of intra-tumoral administration of its Checkvacc oncolytic virotherapy against metastatic triple negative breast cancer.
Imugene said the third cohort was the penultimate stage of the phase I trial, with an expanded final cohort of 12 patients at the recommended phase II dose.
Imugene managing-director Leslie Chong said that “from cohorts one and two we’ve continued to see early positive results in oncolytic virus infection and replication in the [triple negative breast cancer] tumors and importantly there remains no observed toxicity”.
“Checkvacc has the potential to improve clinical response and survival in this indication where there are currently no meaningful treatments,” Ms Chong said.
Imugene was up 2.5 cents or 9.3 percent to 29.5 cents with 92.5 million shares traded.

POLYNOVO

Polynovo says it has enrolled the first of 138 patients in its randomized controlled trial evaluating safety and efficacy of Novosorb Synpath for chronic diabetic foot ulcers.
Polynovo said the primary efficacy endpoint would be the percentage of ulcers fully healed at 12 weeks.
The company said Novosorb Synpath was “designed to promote organized healing by providing a porous network of biodegradable synthetic polymers which act as a template to support the proliferation of vital cells involved in tissue repair”.
Polynovo said that given the number of diabetes patients, it expected enrolment in the US trial to be completed by April 2023.
Polynovo chair David Williams said that surgeons had been using the company’s Novosorb biodegradable temporizing matrix (BTM) for the treatment of diabetic foot ulcers, but it had developed Synpath as a specific product for diabetic foot ulcers and venous leg ulcers.
“The trial will provide valuable data for surgeons and importantly, also put us on the path to reimbursement,” Mr Williams said.
Polynovo chief executive officer Swami Raote said the company was “thrilled to have initiated our trial utilizing Novosorb Synpath for the treatment of chronic diabetic foot ulcers”.
“This critical milestone has us on the road to help more patients with non-healing chronic wounds and to further investigate the benefits of our novel technology for these wound types,” Mr Raote said.
“Synpath is leveraging our successes in the acute care setting with Novosorb BTM and allows us to expand our offering to the outpatient setting for clinicians dedicated to changing the lives of their patients,” Mr Raote said.
Polynovo was unchanged at $2.12 with 4.7 million shares traded.

PATRYS

Patrys says its PAT-DX1 in combination with radiation improves the efficacy of radiation therapy for high-grade glioma, in mice.
Patrys said the study, at the Perth-based Telethon Kids’ Cancer Centre, showed that for 10 mice treated with 25mg/kg dose of PAT-DX1 in combination with radiation therapy had increased median survival of 12 days ($p < 0.0002$) compared to 10 mice receiving radiation alone.
The company said that two of the 10 mice receiving both radiation and PAT-DX1 were “long term survivors”.
Patrys said that “even below its optimal dose PAT-DX1 as a single agent increased survival”.
Patrys managing-director Dr James Campbell said it was “a very exciting result, showing a robust benefit from combining PAT-DX1 with standard of care radiation therapy in high grade glioma, one of the most difficult-to-treat cancers”.
“This, and additional studies funded under the auspices of Cure Brain Foundations’ Clinical Accelerator program, of which our collaborator Prof [Terrance] Johns was the inaugural recipient, will guide us towards optimized therapeutic regimes and timing schedules as we progress PAT-DX1 into the clinic,” Dr Campbell said.
“Having successfully completed our engineering run for PAT-DX1 recently we are well positioned to advance towards the clinic, and excited by the potential of this novel and exciting agent,” Dr Campbell said.
Patrys was up 0.2 cents or 8.3 percent to 2.6 cents with 8.3 million shares traded.

EBR SYSTEMS

EBR says an observational eight human study and a two pig study show that its Wise pacemaker is feasible as a leadless left ventricle septal pacemaker.

Last year, Brandon Capital said EBR had raised $110 million at $1.08 a share in an initial public offer to list on the ASX to develop its wireless stimulation endocardially (Wise) pacemaker (BD: Nov 22, 2022).

Today, EBR said that the combined studies, titled 'Feasibility of leadless left ventricular septal pacing with the Wise-CRT system to target the left bundle branch area: a porcine model and multi-centre patient experience', were published in the journal Heart Rhythm and the full text was available at:
https://www.heartrhythmjournal.com/article/S1547-5271(22)02188-9/fulltext.

The company said results were positive in both the human and pig studies, with successful deployment of the electrode on the left ventricle septum.

EBR said the study showed Wise provided more physiological ventricular activation, and greater battery longevity through a minimized distance from transmitter to electrode, and decreased risk of perforation and pericardial effusion compared to conventional pacing.

The company said this showed the potential of Wise in treating left bundle branch blockages in the heart, which were linked to a greater risk of heart attack-induced death.

EBR chief executive officer John McCutcheon said that the studies "generated important insights into feasibility and potential utility of Wise in the treatment of heart failure through left bundle branch pacing … [and] strengthens the body of data that we have built up in support of Wise over the past few years".

EBR fell two cents or 3.1 percent to 63 cents.

LBT INNOVATIONS

LBT says it is developing an automated plate assessment system for pharmaceutical companies, APAS Pharma, for microbial quality control; along with other products.

LBT said microbial quality control was "a critical process conducted in pharmaceutical manufacturing to ensure the sterility of production environments".

The company said that component of microbial quality control was "settle plate testing, using culture plates to monitor for microbial growth during drug production".

LBT said the tests were "important, with product release dependent on a negative result".

The company said that more than 350 million microbial quality control tests were performed globally each year, with each plate required to be read by two separate microbiologists to ensure data integrity.

LBT said it had completed a proof-of-concept exercise with an unnamed pharmaceutical company to show the suitability of the APAS technology for this application.

The company said that "performance met all target end-point criteria, giving confidence that the APAS platform can successfully be applied to this new application".

LBT research director and APAS inventor Rhys Hill said the company had "developed a number of regulatory cleared analysis modules which is fundamentally where our [intellectual property] and technical leadership has been focused".

LBT said it had made a "major investment" of about $30 million in imaging and artificial intelligence for its APAS Independence and a smaller "desk top" version, to be called the APAS Micro, was in development.

The company said it had APAS Independence modules for urine screening and infection control with new modules "in development for antimicrobial susceptibility testing", screening and early culture plate reading.

LBT was up half a cent or 7.25 percent to 7.4 cents with 1.2 million shares traded.

STARPHARMA

Starpharma says it will design and synthesize dendrimer-enhanced product (DEP) antibody drug conjugates for the Rahway, New Jersey-based Merck Sharp & Dohme.
In 2021, Starpharma said it had an agreement with Merck & Co Inc, known outside the US as Merck Sharp & Dohme, for a pre-clinical research evaluation of its dendrimer enhanced products for antibody drug conjugates (BD: Feb 12, 2022).
Today, the company said the terms of the 12-month agreement were the same as for the research agreement signed in February 2021, with each party maintaining ownership of their own background intellectual property and “research fees … not expected to be material”.
Starpharma said the agreement was subject to industry standard performance and termination provisions.
Starpharma was up 1.5 cents or two percent to 75.5 cents.

TRUSCREEN

Truscreen says its China distributor Siweixiangtai Technology Company has relaunched its Truscreen device in Xinjiang region, following Covid-induced delays.
Truscreen said the Truscreen device was artificial intelligence-enabled and could “detect precancerous and cancerous cervical changes ... via optical and electrical measurements of cervical tissue” circumventing many of the issues with cytology.
The company said that as part of the launch, it delivered 20 Truscreen cervical cancer screening devices, and 12,960 single-use sensors.
Truscreen was up 0.6 cents or 14.6 percent to 4.7 cents.

MACH7 TECHNOLOGIES

Mach7 Technologies says that the Plano, Texas-based AI Visualize has filed an appeal to the dismissal of its recent patent infringement lawsuit.
In July, Mach7 said that the US District Court for the District of Delaware has granted its request to dismiss all claims made by AI Visualize (BD: Jul 13, 2022).
Today, the company said that AI Visualize had appealed the dismissal to the United States Court of Appeals for the Federal Circuit.
Mach7 said it would “continue to defend itself”.
Mach7 fell 6.5 cents or nine percent to 65.5 cents.

MEDLAB

Medlab says the Europe Patent Office has accepted its depression patent relating to its NRGBiotic, and expects the patent to be granted within three months.
Medlab said the patent, titled ‘Treatment for depression and depressive disorders’, would likely provide protection of the technology until 2036.
Last year, the company said that its NRGBiotic combined with an anti-depressant had greater symptom remission over eight weeks than for those patients on the anti-depressant alone ($p < 0.001$) (BD: Feb 11, 2021).
Medlab fell 50 cents or 4.55 percent to $10.50.

LUMOS DIAGNOSTICS

The Sydney-based Ryder Capital says it has become a substantial shareholder in Lumos with 16,643,032 shares (7.93%).
Ryder Capital said that between June 6 and August 9, 2022, it bought 10,924,093 shares in Lumos for $1,086,140, or an average price of 9.94 cents a share.
Lumos was up 1.05 cents or 18.9 percent to 6.6 cents with 5.5 million shares traded.

MEDADVISOR

The South Jordan, Utah-based Cotiviti says its 43,999,999 share-holding in Medadvisor has been diluted from 11.66 percent to 8.60 percent.
Last month, Medadvisor said it had raised $10 million in its institutional rights offer at 14 cents a share and would raise a further $4.6 million in a fully underwritten retail rights offer to acquire Sydney's Guildlink for $9.14 million (BD: Jul 25, 27, 2022).
Medadvisor was up half a cent or 3.1 percent to 16.5 cents.