Biotech Daily

Thursday November 5, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: DIMERIX UP 8%; OSPREY DOWN 5%**

*** PROTEOMICS: 'STUDIES BACK PROMARKERD FOR KIDNEY DISEASE'**

*** SWITZERLAND APPROVES ONCOSIL PANCREATIC CANCER DEVICE**

*** NUHEARA RECEIVES $1.4m R&D TAX INCENTIVE**

*** NOXOPHARM RAISES VEYONDA COVID-19 DOSE**

*** NOXOPHARM LAUNCHES PHARMORAGE FOR SEPSIS**

*** INCANNEX: 'IHL-675A BEATS CBD' FOR INFLAMMATION, IN-VITRO**

*** MGC 35% REM REPORT 1st STRIKE; ARTEMIC COVID-19 TRIAL DOSED**

*** PATRYS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** RECCE TAKES 'ANTI-VIRAL RESULTS' TRADING HALT TO SUSPENSION**

*** AUSTRALIAN ETHICAL TAKES 6.5% OF MACH7**

MARKET REPORT

The Australian stock market was up 1.28 percent on Thursday November 5, 2020, allegedly related to the US election, with the ASX200 up 77.5 points to 6,139.6 points. Twenty-two of the Biotech Daily Top 40 stocks were up, seven fell, nine traded unchanged and two were untraded. All three Big Caps were up.

Dimerix was the best, up two cents or 7.8 percent to 27.5 cents, with 949,787 shares traded. Oncosil, Paradigm and Telix climbed more than six percent; Amplia and Kazia were up more than five percent; Genetic Signatures and Polynovo improved more than four percent; Antisense, CSL, Immutep, Optiscan, Pro Medicus and Resmed were up more than three percent; Cochlear, Cynata, Impedimed and Mesoblast rose more than two percent; Avita, Imugene, Orthocell, Universal Biosensors and Volpara were up more than one percent, with Clinuvel and Starpharma up by less than one percent.

Osprey led the falls, down 0.1 cents or 4.8 percent to two cents, with 2.8 million shares traded, followed by Actinogen down 4.55 percent to 2.1 cents with 3.4 million shares traded. Nanosonics lost 3.1 percent; Neuren shed 2.4 percent; Medical Developments and Prescient were down more than one percent; with Opthea down 0.45 percent.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says two studies and an industry application note show “the robust technical performance of the Promarkerd predictive test for diabetic kidney disease”.

Proteomics said the studies and note, all co-authored by Proteomics chief executive officer Dr Richard Lipscombe, showed a high correlation between the original Promarkerd mass spectrometry (MS) and the more recently developed Promarkerd immune-assay (IA) platforms and “proves the reliability of the Promarkerd test system”.

The first research article, titled ‘A robust multiplex immunoaffinity mass spectrometry assay (Promarkerd) for clinical prediction of diabetic kidney disease’, was published in the journal Clinical Proteomics and available at: https://bit.ly/3mQOxSg.

The article concluded that “an immunoaffinity capture targeted mass spectrometry assay was developed and optimized … [showing] statistically comparable results to those obtained from the original immune-depletion method and was also able to provide comparable results when deployed to an independent laboratory”.

“Taking a research grade assay and optimizing to a clinical grade workflow provides insights into the future of multiplex biomarker measurement with an immunoaffinity mass spectrometry foundation,” the article concluded.

“In the current format the Promarkerd immune-affinity assay has the potential to make a significant impact on prediction of diabetic kidney disease with consequent benefit to patients,” the journal article concluded.

An industry application note, titled ‘From Nanoflow to Standard Flow LC/MS for Routine Quantitative Plasma Proteomics in Diabetic Kidney Disease Research’ published by Agilent Technologies said that “successful and reproducible analysis of the eight peptides in whole plasma comparable to depleted plasma analysis highlights the analytical sensitivity and robustness offered by the 6495 LC/TQ for routine protein measurement in biomarker research”.

The abstract is available at: https://bit.ly/34VuQmbt.

The second research article, titled ‘The New and the Old: Platform Cross-Validation of Immunoaffinity Mass Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease’ was published in the journal Proteomes and an abstract is available at: https://pubmed.ncbi.nlm.nih.gov/33126588/.

“The performance characteristics of the two technology platforms were compared using a cohort of 100 samples, with Promarkerd test scores demonstrating a high correlation (R = 0.97),” the abstract said. “These technologies illustrate the potential for large scale, high throughput clinical applications of proteomics now and into the future.”

Proteomics said that there was high correlation between the advanced mass spectrometry platform and the traditional immunoassay enzyme-linked immune-sorbant assay (Elisa) platform, “with more than 90 percent of the samples achieving Promarkerd risk scores within five percent of the other platform's score”.

“Both technology platforms were successfully validated for assay reproducibility, robustness and stability for the Promarkerd test system,” the company said.

Proteomics said the results “form an essential basis for regulatory approvals related to the Promarkerd test system and its adoption by pathology laboratories worldwide” and showed the potential for adoption of the Promarker platform in clinical practice.

Dr Lipscombe said that “this type of robust performance data is essential in achieving regulatory approvals for the Promarkerd test system”.

“Not only do the results prove the test can be used reliably in today's clinical laboratories, but they also offer an insight into the use of the Promarker platform in clinical practice in the decades to come,” Dr Lipscombe said.

Proteomics was unchanged at 50 cents.

ONCOSIL MEDICAL

Oncosil says it has received regulatory approval in Switzerland to market and sell its Oncosil pancreatic cancer radiation device.
In April, Oncosil said it had Conformité Européenne (CE) mark approval and breakthrough designation for the device, which covered the European Union (BD: Apr 1, 2020).
Today, the company said that as Switzerland was not an EU Member State a separate registration filing was required for approval.
Oncosil said that Switzerland was "an attractive market … [as] healthcare spending per capita is high in comparison to other European markets and private medical insurance is compulsory for all persons in Switzerland".
The company said it had regulatory clearance in Malaysia, Singapore and New Zealand.
Oncosil was up one cent or 6.7 percent to 16 cents with 6.7 million shares traded.

NUHEARA

Nuheara says it has received $ $1,395,004 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Nuheara said the rebate related to expenditure for the year to June 30, 2020.
Nuheara was unchanged at 4.3 cents with 4.1 million shares traded.

NOXOPHARM

Noxopharm says it will enrol a further 12 patients in its phase Ib study of Veyonda, or NOX66, for Covid-19, following a safety review of the first two cohorts of the trial.
In April, Noxopharm said that idronoxil, the active ingredient in Veyonda, inhibited a pathway of the cytokine storm resulting from severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) infection and it would seek US Food and Drug Administration guidance for a Covid-19 trial (BD: Apr 1, 21, 2020).
Last month, the company said it had enrolled six patients in the first two cohorts of the study and would administer 400mg of Veyonda to the first cohort and 600mg to the second cohort (BD: Oct 26, 2020).
Today, Noxopharm said the study safety committee conducted the safety review after the initial six patients had received a minimum 14-days of treatment and approved the next 12 patients, which would be dosed with either 800mg or 1200mg of Veyonda.
Noxopharm said the dose-increasing stage of the trial was at three sites in Moldova.
Noxopharm was up one cent or two percent to 50 cents.

NOXOPHARM

Noxopharm says it has partnered with the Hudson Institute of Medical Research and the Australian National University to form subsidiary Pharmorage Pty Ltd for sepsis.
Noxopharm said it had a "royalty-based collaboration" with Melbourne's Hudson Institute, which would conduct laboratory studies and provide expertize in the stimulator of interferon genes (Sting) signalling path, which was associated with inflammation in viral and bacterial infections, cancer and cell damage.
The company said Pharmorage planned to include autoimmunity through a research collaboration with Canberra's Australian National University, which would conduct laboratory studies on a sponsored research basis.
Noxopharm did not provide further details of its agreements with the Hudson Institute or the Australian National University.

INCANNEX HEALTHCARE (FORMERLY IMPRESSION HEALTHCARE)

Incannex says its IHL-675A cannabidiol-hydroxychloroquine beats cannabidiol alone by up-to 767 percent for cytokine inhibition 24 hours after drug administration, in-vitro.
Incannex said its IHL-675A for sepsis associated acute respiratory distress syndrome combined cannabidiol (CBD) and hydroxychloroquine which acted "synergistically to inhibit production of key inflammatory cytokines in in-vitro pre-clinical studies".
The company said it tested the anti-inflammatory capabilities of IHL-675A and CBD alone using human peripheral blood mononuclear cells stimulated with bacterial lipo-poly-saccharide to induce an inflammatory response.
Incannex said the inflammatory response was assessed by measuring cytokine levels in the culture medium after 24 hours, where a reduction in cytokine levels in response to drug treatment was indicative of anti-inflammatory activity.
The company said it would use in-vitro data on the IHL-675A combination to refine the dosing parameters of an anti-inflammatory study in mice (BD: Jul 17, 2020).
Incannex was up 0.9 cents or 11.5 percent to 8.7 cents with 9.5 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says its annual general meeting passed all resolutions, but earning a first strike against the remuneration report, with 35.28 percent of votes opposed.
MGC said the remuneration report had 47,976,903 votes (35.28%) against and 80,765,734 votes (59.39%) in favor, earning a 'first strike'.
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 the directors must stand for re-election.
The company said the vote to issue 1,000,000 shares to Daniel Erdman for business development consultancy services had the largest number of opposition votes, with 48,811,967 votes (19.04%) against and 207,591,949 votes (80.96%) in favor.
The issue of shares to chief medical officer Dr Jonathan Grunfeld and Lenis Farmacevtika, the replacement of the constitution, the placement capacity, the issue of shares to Cannvalate, Onassis Holdings, Prohibition Partners, Grow Biotech, Mercer Street Fund, the issue of convertible notes and election of directors Brett Mitchell and Evan Hayes all faced more than 42 million votes against or about 17 percent of the meeting, with the ratification of the prior issue of shares to employees and consultants passed easily.
MGC's most recent Appendix 2A new issue announcement said the company had 1,640,791,907 shares on issue, meaning that the votes against the issue of shares to Mr Erdman amounted to 2.97 percent of the company, not sufficient to requisition extraordinary general meetings.
Separately, the company said it had completed dosing in its 50-patient phase II trial of its artemisinin and curcumin Artemic for Covid-19 (BD: Apr 17, Oct 14, 2020).
MGC said it expected the full results to be published "in the next month".
MGC was up 0.3 cents or 15.0 percent to 2.3 cents with 9.9 million shares traded.

PATRYS

Patrys has requested a trading halt pending an announcement "in relation to a capital raising".
Trading will resume on November 9, 2020 or on an earlier announcement.
Patrys last traded at 2.1 cents.

RECCE PHARMACEUTICALS

Recce has requested a voluntary suspension to follow the trading halt requested in relation to an “announcement relating to anti-viral testing results” (BD: Nov 3, 2020).
Trading will resume on November 9, 2020 or on an earlier announcement.
Recce last traded at 95 cents.

MACH7 TECHNOLOGIES

Australian Ethical Investment says it has increased its substantial shareholding in Mach7 from 11,857,136 shares (5.45%) to 15,141,322 (6.45%).
The Sydney-based Australian Ethical said that June 30 and November 2, 2020 it bought 3,284,186 shares for $3,018,719 or an average of 91.9 cents a share.
Mach7 was up 1.5 cents or 1.6 percent to 96.5 cents.