Biotech Daily

Monday June 6, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRESCIENT UP 11%; OPTHEA DOWN 7%**

*** LUMOS $11.2m RIGHTS OFFER; DOUG WARD CEO ON $576k**

*** CLARITY: FDA OKAYS SAR-BOMBESIN PROSTATE CANCER IND**

*** S&P ASX INDICES: POLYNOVO, VOLPARA, PLATINUM DEMOTED**

*** IMMUTEP: IMP321 'FAVORABLE EFFICACY FOR NSCLC'**

*** PROTEOMICS: 'PROMARKERD PREDICTS LATE-STAGE KIDNEY DECLINE'**

*** NYRADA: NYR-BI02 TARGETS TRPC ION CHANNELS**

*** VGI VOTES 99.99% FOR INVICTUS DEMERGER**

*** RESAPP EXTENDS PFIZER DEAL SUSPENSION**

*** RADIOPHARM APPOINTS PROF LEILA ALLAND DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.45 percent on Monday June 6, 2022, with the ASX200 down 32.5 points to 7,206.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 25 fell and four traded unchanged.

Prescient was the best, up two cents or 11.1 percent to 20 cents, with 2.8 million shares traded. Orthocell climbed 6.9 percent; Clinuvel and Next Science improved more than four percent; Compumedics rose 2.9 percent; Avita, Cynata and Telix were up one percent or more; with CSL, Neuren, Pro Medicus and Starpharma up by less than one percent.

Opthea led the falls, down 10 cents or 7.4 percent to $1.25, with 153,299 shares traded.

Resonance retreated 6.7 percent; Actinogen, Dimerix, Immutep, Mesoblast and Micro-X were down more than five percent; Cyclopharm, Paradigm, Patrys, Polynovo and Volpara fell four percent or more; Alcidion, Amplia and Universal Biosensors were down more than three percent; Emvision, Nova Eye and Pharmaxis shed more than two percent; Atomo, Genetic Signatures, Impedimed and Nanosonics were down more than one percent; with Cochlear, Kazia, Medical Developments, Proteomics and Resmed down by less than one percent.

LUMOS DIAGNOSTICS

Lumos says it expects to raise $11.2m in an underwritten rights offer at 19 cents a share, and has appointed Doug Ward as chief executive officer, starting on $576,364 a year.
Lumos said the one-for-2.55 pro-rata, entitlement offer was a 22.4 percent discount to the last closing price of 24.5 cents a share, on June 1, 2022.
The company said the offer included one free option for every new share issued, exercisable at 30 cents each by November 30, 2022.
Lumos said the institutional offer was expected to close on June 7, and the retail offer had a record date of June 8, would open on June 10 and close on June 23, 2022.
Lumos said the offer would fully fund activities to the end of 2022, including infrastructure and capacity expansion, sales and marketing, regulatory, clinical and quality, development of its test pipeline and technology platform development.
The company said that Bell Potter Securities and Wilsons Corporate Finance were joint lead managers and underwriters to the offer.
Lumos said it would undertake a cost reduction program, targeting a reduction of its monthly cash burn rate to below $1.4 million a month.
Last year, Lumos said it had raised $63 million in its initial public offer at $1.25 a share (BD: Jul 5, 2021).
In April the company's Appendix 4C quarterly report said it had $US6,025,000 ($A8,361,500) in customers receipts for the three months to March 31, 2022, a cash burn of $US3,285,000 for the period and $US6,578,000 in cash and equivalents.
Lumos said Mr Ward was expected to start in mid-June 2022, on a base salary of $US415,000 ($A576,364) a year with the potential to increase to $US485,000.
Lumos said it would provide Mr ward a one-off payment of $US120,000 as a lost bonus from his current employer, subject to the company receiving US Food and Drug Administration clearance for its Febridx finger-prick blood test differentiating viral from bacterial infections, or $US5 million in product sales.
The company said it would also provide Mr Ward 7.5 million options exercisable at 30 cents each within seven years and vesting in two tranches over four years.
Lumos was in a trading halt and last traded at 24.5 cents.

CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration has approved its investigational new drug application for a sarcophagine-bombesin for prostate cancer imaging trial.
Clarity said the approval allowed it to proceed with the 50-petient, single-arm, open-label, US-based, phase II, 64-copper sarcophagine (SAR)-bombesin positron emission tomography (PET) imaging trial in patients with prostate-specific membrane antigen (PSMA)-negative biochemical recurrence of prostate cancer following definitive therapy.
The company said the copper-64 SAR-bombesin in biochemical recurrence of prostate cancer (Sabre) study built on data from its pilot breast cancer trial (BD: Oct 19, 2021).
Clarity said that about 20 percent of prostate cancers with biochemical recurrence were PSMA-PET negative, meaning that patients were unlikely to respond to therapeutic PSMA-targeted products, leaving few treatment options available.
The company said that SAR-bombesin targeted the gastrin-releasing peptide receptor found on prostate and other cancers, meaning the product could "offer valuable imaging and therapeutic options for not only PSMA negative patients, but also the large number of patients that have the target receptor on their cancers".
Clarity chair Dr Alan Taylor said that US FDA approval was a "significant milestone".
Clarity fell one cent or 2.1 percent to 46.5 cents.

STANDARD & POOR'S DOW JONES INDICES

Two biotechnology companies and Platinum Asset Management will be demoted in changes to Standard & Poor's ASX indices, effective from June 20, 2022.
Standard & Poor's said Polynovo and investment fund Platinum would be removed from the ASX200, with Volpara removed from the ASX All Technology Index.
Previously, Standard & Poor's has told Biotech Daily that inclusion in the indices is based solely on market capitalization.
The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.
Polynovo fell five cents or 4.2 percent to $1.135 with 2.6 million shares traded.
Volpara fell three cents or 4.4 percent to 65.5 cents.

IMMUTEP

Immutep says data from its 114-patient Tacti-002 phase II trial of IMP321 with pembrolizumab shows "favorable efficacy in first line non-small cell lung carcinoma".
Immutep said data from the trial, titled 'A Phase II study (Tacti-002) in 1st line metastatic non-small cell lung carcinoma investigating eftilagimod alpha (soluble LAG-3 protein) and pembrolizumab: updated results from a PD-L1 unselected population', was presented at the American Society of Clinical Oncology's meeting, in Chicago from June 3 to 7, 2022.
Last month, the company said that it had presented data from its two active immune-therapies (Tacti) Tacti-002 phase II trial of IMP321, or eftilagimod alpha, with pembrolizumab, or Keytruda, which showed "favorable anti-tumor activity in first line non-small cell lung cancer" (BD: May 27, 2022).
Today, Immutep said data from Tacti-002, for which the cut-off date was April 15, 2022, showed an improved overall response rate in 44 of 114 patients (38.6%), compared to 28 of 75 patients (37.3%) in the previous month, and with an improved disease control rate in 84 of 114 patients (73.7%) compared to 55 of 73 patients (73.3%), last month.
Immutep said that the IMP321 and pembrolizumab combination was safe and well-tolerated, with 9.6 percent of patients discontinuing due to related adverse effects.
Immutep chief medical officer Dr Frederic Triebel said the overall response rate compared favorably to historical results from anti-programmed cell death-ligand-1 (PD-1) monotherapies where response rates in PD-L1 all-comer trials were "typically around 20 percent".
"We are particularly pleased to see encouraging responses across all PDL1 status groups, showing that efti [IMP321] may kick start an anti-tumor immune response even in patients with no or low PD-L1 expression," Dr Triebel said.
Immutep chief executive officer Marc Voigt said the data was "encouraging for patients, as there is an unmet medical need particularly for those with [non-small cell lung carcinoma] with no or low PD-L1 expression".
"We enlarged this part of the study in order to see if the strong earlier results in a smaller group of patients are holding true in more than a hundred patients," Mr Voigt said.
"By biotech standards, we consider this to be a large patient population for a phase II trial," Mr Voigt said.
"For Immutep, these highly favorable results are of strategic importance, as they support late-stage development for an attractive and very large addressable market," Mr Voigt said.
The company said it expected to release further results from the study in the second half of 2022.
Immutep fell 2.5 cents or 5.8 percent to 40.5 cents with three million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says a study of its Promarkerd diagnostic test for kidney disease has shown its potential ability to predict late-stage renal decline, as well as early stage.

Proteomics said the study was based on a post-hoc analysis of 3,525 people with type 2 diabetes, followed for three years in the completed canagliflozin cardiovascular assessment (Canvas) study, in collaboration with the New Jersey-based Janssen Research and Development.

The company said a poster, titled 'Promarkerd Predicts Late-Stage Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (Canvas)', was presented at the American Diabetes Association meeting in New Orleans, from June 3 to 7, 2022.

Proteomics said Promarkerd could predict the onset of diabetic kidney disease up to four years in advance and this study extended the potential use of Promarkerd to predict a further decline in renal function among people who already had kidney disease.

The company said the key findings were that "moderate and high-risk Promarkerd scores were increasingly prognostic for adverse renal and cardio outcomes" and Promarkerd was "a significant independent predictor of late-stage outcomes even after adjusting for other clinical risk factors".

Proteomics managing-director Dr Richard Lipscombe said that "this exploratory data is promising and indicates the use of Promarkerd may be expanded to include people with existing kidney disease".

"However, the current Promarkerd algorithm has been optimized for the prediction of early onset of [diabetic kidney disease] and the test algorithm would need further optimization for this new use," Dr Lipscombe said. "The results also suggested further studies were warranted to explore whether Promarkerd could predict additional cardiovascular outcomes, such as heart failure and stroke."

Proteomics fell half a cent or 0.5 percent to 92 cents.

NYRADA

Nyrada says the biological target for its brain injury program are versatile transient receptor potential canonical (TRPC) ion channels.

Nyrada said that TRPC ion channels were present on the surface of brain cells and allowed calcium to enter the cell, and following a brain injury, such as a stroke or concussion, these channels were constantly activated, allowing sustained calcium entry into the cells, which in turn caused cell death.

The company said its brain injury drug candidate NYR-BI02 was a potent blocker of three sub-types of the channel, TRPC3, TRPC6 and TRPC7, and was able to cross the blood-brain-barrier indicating it could reach the injured brain at a therapeutic level.

Nyrada company said that animal studies and published literature showed the three TRPC channel sub-types facilitated a secondary injury pathway, which led to an undesirable larger injury following a traumatic brain injury or stroke, responsible for poor patient outcomes, such as increased disability and reduced patient survival or quality of life.

Nyrada said there was no US Food and Drug Administration approved small molecule blocker of the three ion channel sub-types, and it had filed a provisional patent covering "a library of molecules that block these channels".

Nyrada said it would conduct a phase I brain injury study to assess the safety, tolerability and pharmaco-kinetics of NYR-BI02 in up to 40 patients, expected to begin this year, pending scale-up, drug manufacturing and ethics approval.

Nyrada fell one cent or 6.25 percent to 15 cents.

VGI HEALTH TECHNOLOGY (FORMERLY AZURE, INVICTUS BIOPHARMA)

VGI says that all four extraordinary general meeting resolutions relating to the Invictus demerger passed easily.

In February, VGI said that Invictus would raise $2,300,000 to demerge from the National (Newcastle) Stock Exchange-listed entity, with VGI retaining 20 percent of the unlisted company (BD: Feb 14, 2022).

Today, VGI said that all resolutions were passed with more than 31.3 million votes in favor and up to 28,369 votes against.

On the NSX, VGI was untraded at 10 cents.

RESAPP HEALTH

Resapp has requested a further extension to its voluntary suspension pending “an announcement … as to the status of the proposed acquisition by Pfizer Australia”.

Last week, Resapp requested a voluntary suspension to follow the trading halt to consider a draft independent expert report (BD: Jun 2; May 31, 2022).

In April, the company said Pfizer Australia would offer 11.5 cents a share, a 27.8 percent premium, to buy the company, valuing it at $100 million (BD: Apr 11, 2022).

Today, Resapp said it requested the voluntary suspension until June 8, 2022 when it expected to release the announcement.

Resapp last traded at 11 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has appointed Prof Leila Alland as a non-executive director, effective from today, June 6, 2022.

Radiopharm said Prof Alland was a paediatric haematologist-oncologist, currently working for the Cranbury, New Jersey-based PMV Pharmaceuticals as chief medical officer and was a director of several bio-pharmaceutical companies.

The company said Prof Alland was previously the chief medical officer of Affimed and an executive at Astrazeneca, Bristol-Myers Squibb, Novartis and Schering-Plough.

Radiopharm said Prof Allan held a Doctor of Medicine from the New York University School of Medicine and was an assistant professor of paediatrics at the Albert Einstein College of Medicine in New York.

Radiopharm fell one cent or 5.4 percent to 17.5 cents.