Biotech Daily

Tuesday August 2, 2022

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: PARADIGM UP 12%; ATOMO DOWN 15%**

*** CSL ACQUIRES VIFOR, HERVÉ GISSEROT G-M**

*** AMPLIA DOSES 1st AMP945 PANCREATIC CANCER TRIAL PATIENT**

*** TELIX FILES FOR ILLUCCIX, TLX250-CDX CHINA TRIALS**

*** ADHERIUM SUBMITS HAILIE GSK SENSOR US 510(K) APPLICATION**

*** PROTEOMICS: 'DOCTORS PREFER PROMARKERD' FOR TYPE 2 DIABETES**

*** LUMOS SHUTS SARASOTA FACILITY TO CUT COSTS**

*** INCANNEX HIRES CURIA TO MANUFACTURE IHL-216A**

*** MEDLAB NSW UNI LABORATORY LEASE WORTH $90k PA**

*** NOXOPHARM: 1200mg VEYONDA 'SAFE, WELL-TOLERATED'**

*** ASX REMOVES PALLA FROM OFFICIAL LIST**

*** CRESO REQUESTS 'CAPITAL RAISE' SUSPENSION EXTENSION**

*** GUILD GROUP TAKES 13% OF MEDADVISOR**

*** REGAL FUNDS DILUTED TO 7% IN MEDADVISOR**

*** LIFE BIOSCIENCES REDUCES TO 7.5% IN ALTERITY**

*** ARTRYA APPOINTS DR JACQUE SOKOLOV US DIRECTOR**

*** NICOLE VAN DER WEERDEN REPLACES HEXIMA CEO MICHAEL ALDRIDGE**

*** DR GISELA MAUTNER REPLACES NYRADA DIRECTOR PETER MARKS**

*** AUSBIOTECH, MEDICINES AUSTRALIA CELL & GENE CATALYST**

MARKET REPORT

The Australian stock market edged up 0.07 percent on Tuesday August 2, 2022 with the ASX200 up 5.1 points to 6,998.1 points. Sixteen of the Biotech Daily Top 40 stocks were up, 21 fell and three traded unchanged.

Paradigm was the best for the second day in a row, on no news, up 15 cents or 12.1 percent to $1.39, with 626,131 shares traded. Genetic Signatures climbed 6.7 percent; Pharmaxis was up 5.5 percent; Next Science and Patrys rose more than four percent; Amplia, Avita and Telix were up three percent or more; Clinuvel, Compumedics, Imugene, Kazia, Mesoblast, Nanosonics and Pro Medicus rose two percent or more; Antisense was up 1.3 percent; with Cochlear and CSL up by less than one percent.

Atomo led the falls, down 1.2 cents or 15.4 percent to 6.6 cents, with 1.4 million shares traded. Neuren lost 8.4 percent; Alcidion and Micro-X were down more than six percent; Prescient was down 5.6 percent; Actinogen, Emvision, Nova Eye and Volpara fell more than four percent; Dimerix, Immutep, Proteomics, Universal Biosensors and Uscom were down three percent or more; Medical Developments, Orthocell and Resonance shed two percent or more; Cynata, Polynovo and Starpharma were down more than one percent; with Cyclopharm and Resmed down by less than one percent.

CSL

CSL says it has completed its acquisition of the St Gallen, Switzerland-based Vifor Pharma AG and appointed Hervé Gisserot as its general-manager.

Last year, CSL said it would acquire Vifor for $US11.7 billion ($A16.4 billion) for its renal disease and iron deficiency expertise (BD: Dec 14, 2021).

At that time, the company said it would launch “an all-cash public tender offer” to acquire all publicly held Vifor shares for $US179.25 per share, a 40 percent premium to the 60-day volume weighted average price to December 1, 2021.

In March, CSL said it had received applications for 74 percent of Vifor and declared the offer was “successful” (BD: Mar 4, 2022).

Today, CSL said it expected the acquisition would occur by August 9, 2022 and it would hold more than 97 percent of Vifor shares upon completion.

The company said it would cancel all remaining Vifor shares, “in accordance with Swiss takeover rules … [and] apply for the delisting of Vifor shares on the Swiss Exchange”.

CSL said Mr Gisserot was the Vifor chief commercial officer and previously worked for Glaxosmithkline for 13 years as head of pharmaceuticals and vaccines for Greater China and intercontinental, among other roles.

The company said Mr Gisserot had worked for Sanofi-Aventis, Aventis, Rhone-Poulenc Rorer and Fournier Group.

CSL managing-director Paul Perreault said “we are excited to complete the acquisition of Vifor Pharma - enhancing CSL’s well-established patient focus and ability to protect the health of those facing a range of rare and serious medical conditions”.

“Joining CSL, the Vifor business adds near-term value along with a clear path to long-term sustainable growth,” Mr Perreault said. “It also adds an outstanding management team, along with a high-value and complementary portfolio of products and market leading position in the nephrology and iron deficiency spaces.”

CSL was up $1.94 or 0.7 percent to $296.85 with 602,149 shares traded.

AMPLIA THERAPEUTICS

Amplia says it has dosed the first of 12 patients in its phase Ib/IIa, 'Accent,' open-label trial of focal adhesion kinase inhibitor AMP945 for advanced pancreatic cancer.
Amplia said the trial would study the pharmaco-kinetics, safety and efficacy of AMP945 in combination with nab-paclitaxel (Abraxane) and gemcitabine for pancreatic cancer.
The company said the first stage of the trial was an ascending dose, single-arm, open-label study to select an optimal dose of AMP945, assessing safety, tolerability, pharmaco-kinetics, pharmaco-dynamics and preliminary efficacy of AMP945 in combination with gemcitabine and nab-paclitaxel, in first-line patients with advanced pancreatic cancer.
Amplia said it expected that up to four dose levels of AMP945 would be assessed, and if all four dose levels were required, it would take about nine months to complete.
The company said the second stage was an up-to 26-patient, single-arm, open-label study to assess the optimal dose of AMP945 in combination with gemcitabine and nab-paclitaxel, with the primary endpoint of objective response rate of patients to treatment.
Amplia managing-director Dr John Lambert said "this is another exciting milestone marking the achievements and growth of our company and we're very proud of our team's efforts in starting up the Accent trial".
"The work we have done to date with AMP945 both in the clinic and in preclinical models of pancreatic cancer tells us that AMP945 deserves to be clinically tested in this dangerous type of cancer," Dr Lambert said.
Amplia was up 0.3 cents or 3.2 percent to 9.8 cents.

TELIX PHARMACEUTICALS

Telix says it has filed applications to China for trial approvals for its TLX591-CDx Illuccix kit for prostate cancer imaging and TLX250-CDx for kidney cancer imaging.
Telix said that the investigational new drug applications had been filed by its partner Grand Pharma to China's National Medical Products Administration.
In 2020, the company said it had an exclusive up-to $US315 million ($A450 million) plus royalties 10-year partnership with the Hong Kong-based China Grand Pharmaceutical and Healthcare Holdings for the development, sales, marketing and distribution of its prostate, renal and brain cancer imaging and therapeutic molecularly-targeted radiation products in Greater China (BD: Nov 2, 2020).
Today, Telix said the TLX591-CDx application had been accepted for review for a pivotal phase III study to bridge to the US Food and Drug Administration approval of Illuccix.
The company said an application for a pivotal phase III study had been accepted for a trial that would bridge to its phase III Zircon trial of TLX250-CDx (89-zirconium-girentuximab), for the imaging of renal cell carcinoma with position emission tomography.
Telix said the phase III bridging studies of TLX591-CDx and TLX250-CDx were required to provide data in an exclusively Chinese population to establish that efficacy of the investigational products was equivalent in Chinese and Western populations, and both studies were expected to be multi-centre, enrolling about 100 patients.
Telix Asia-Pacific chief executive officer Dr David Cade said the region was "a major market opportunity, being driven by increasing cancer incidence rates and an investment in installation of [positron emission tomography and computed tomography] cameras in markets such as China and India".
Telix said that in China, 115,000 men were diagnosed with prostate cancer each year, increasing by about six percent each year and 73,000 people were diagnosed with renal cell carcinoma each year.
Telix was up 24 cents or 3.4 percent to $7.34 with 1.2 million shares traded.

ADHERIUM

Adherium says it has submitted its 510(k) application to the US Food and Drug Administration to connect its Hailie sensors to Glaxosmithkline inhaler users.

Adherium said the submission would connect Glaxosmithkline Ventolin, Advair and Flovent inhaler users with its next generation Hailie sensor with physiological measures.

In March, the company said it had filed its 510(k) application to the FDA to connect its next generation Hailie sensor to Glaxosmithkline Ellipta inhalers (BD: Mar 7, 2022).

Today, the company said it had 510(k) clearance for "91 percent of the US top 20 branded inhalers for adherence usage enabling remote therapeutic monitoring reimbursement codes, and 32 percent coverage for physiological parameters enabling the remote physiological monitoring reimbursement codes".

Adherium head of quality, regulator and clinical affairs Tara Creaven-Capasso said that submitting the application was "another development milestone towards our vision of enabling healthcare providers to enhance patient care by capturing clinical data and supporting patient management".

"This 510(k) submission marks, once again, execution on our strategy and delivering on our product roadmap milestones," Ms Creaven-Capasso said.

Adherium was unchanged at 1.1 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says a study found its Promarkerd blood test for diabetic kidney disease was ranked as "more important to physicians than current standard-of-care tests".

Proteomics said the study, titled 'Evaluation of the clinical utility of the Promarkerd in-vitro test in predicting diabetic kidney disease and rapid renal decline through a conjoint analysis' was published by the US Public Library of Science journal PLOS One at: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0271740.

The company said Promarkerd used a blood test to detect a fingerprint of the early onset of diabetic kidney disease, and the study conducted with the Raleigh, North Carolina-based Veranex Solutions, surveyed 400 US physicians and endocrinologists, who assessed 42 real-life scenarios for patients with type 2 diabetes.

Proteomics said Promarkerd risk scores would "significantly impact physician decision marking" with 78 percent of physicians in the study saying they were "very or extremely likely" to order the Promarkerd test for their type 2 diabetes patients.

The company said the Promarkerd results "consistently ranked as the first or second-most important attribute driving physician decision-making across the specified outcomes of disease monitoring frequency, prescription of renal protective drugs (SGLT2 inhibitors) and ongoing use of other drugs for diabetes management, such as [angiotensin-converting enzyme]-inhibitors and ibuprofen".

Proteomics managing-director Dr Richard Lipscombe said the survey showed Promarkerd results ranked "as more important to physicians than current standard-of-care tests estimated glomerular filtration rate (eGFR) and urinary albumin-creatinine ratio (ACR)".

Senior study author Dr Alexander Turchin said that "when presented with moderate or high-risk Promarkerd results, physicians were more likely to implement reno-protective changes - such as increasing monitoring frequency, prescribing SGLT2 inhibitors or replacing ibuprofen - than if they did not have the Promarkerd test results".

Dr Turchin said the changes could help avoid end-stage interventions such as dialysis and kidney transplant and "when presented with low-risk Promarkerd results, the likelihood of aggressive treatment and health care resource utilization reduced".

Proteomics fell three cents or 3.35 percent to 86.5 cents.

LUMOS DIAGNOSTICS

Lumos says it will close its facility in Sarasota, Florida as part of its program to reduce its operating cash burn.

Last week, Lumos said it had 1.71 quarters of funding, and proposed to cut costs as well as "explore additional financing options" (BD: Jul 29, 2022).

Today, the company said it expected to finishing closing the facility in "late September to early October", and that it expected the proceeds from the return and sale of assets would "cover the majority of costs" of the closure but reduce the cash burn through the elimination of the ongoing leasing and operating costs associated with the Sarasota site.

Lumos chief executive officer Doug Ward said "even as we built out our pipeline with new commercial services customers, I am confident that our Carlsbad [California] facility has sufficient capabilities and capacity to meet our near term needs for our growing business".

Lumos fell 0.3 cents or 5.7 percent to five cents.

INCANNEX HEALTHCARE

Incannex says it has hired Curia Global Inc to develop and manufacture its good manufacturing practice-grade IHL-216A for concussion and traumatic brain injuries.

Incannex said the inhaled, marijuana-based IHL-216A was a combination of cannabidiol with any volatile anaesthetic agent, including isoflurane, and was designed to be administered soon after head trauma to reduce secondary brain injuries that lead to neurological deficits.

The company said the Albany, New York-based Curia would "scale-up the fill-finish manufacture of IHL-216A in compliance with current good manufacturing practice", as well as "generate data on the quality and stability of IHL-216A to support future regulatory filings, including a US Food and Drug Administration pre-investigation new drug package and subsequent [investigational new drug] application".

Incannex said the first batch of IHL-216A would be used in its phase I clinical trial, expected to begin once feedback on its development plan was received from the US Food and Drug Administration, in late 2022.

Incannex chief scientific officer Dr Mark Bleackley said that scaling-up IHL-216A was "an exciting step in the development of our product and represents a critical milestone for delivering an inhaled drug, such as IHL-216A".

"Its manufacture will facilitate investigation of the product in the well-controlled clinical trials we are designing, with feedback from FDA, to assess the safety and therapeutic benefit in patients with traumatic brain injuries," Dr Bleackley said.

Incannex was up one cent or 5.3 percent to 20 cents with 3.7 million shares traded.

MEDLAB CLINICAL

Medlab says the laboratory lease and collaboration with the University of New South Wales, will cost $90,000 a year, compared to $240,000 for its Alexandria facility.

Yesterday, Medlab said it had a laboratory lease agreement with the University of New South Wales, building on its Nanocelle research program (BD: Aug 1, 2022).

At that time, the company said the closure of its Alexandria facility, the opening of pharmaceutical facilities in Botany and the laboratory lease with the University, would provide it with "significant operational expenditure savings and new research development capabilities and opportunities".

Medlab is conducting a 150-to-one consolidation with Commsec Iress saying the MDCDA shares were at $13.20. The company closed yesterday at 8.8 cents (x 150 = $13.20).

NOXOPHARM

Noxopharm says patients treated with 1200 milligrams of Veyonda in its phase II, dose-expansion and escalation trial for metastatic cancers showed safety and tolerability.
Noxopharm said the 'Darrt-2' trial was a dose-expansion and dose-escalation study of Veyonda, or NOX66, in combination with external beam radiotherapy to treat patients with progressive, metastatic prostate, breast or lung cancers that had failed standard treatment and were eligible for low-dose, palliative external beam radiotherapy to a single lesion, conducted at 15 sites in Australia, the US, France, and Hungary.
The company said the second dose cohort of patients in the trial was treated with 1200mg of Veyonda, which was found to be "safe and well tolerated", and that approval had been given to continue the trial into the third cohort of patients to receive 1600mg doses.
Noxopharm chief executive officer Dr Gisela Mautner said "the Darrt-2 trial continues to gain momentum as we have passed another significant milestone with a positive safety data review, and we are now recruiting patients in leading cancer hospitals across three continents".
Noxopharm was unchanged at 24 cents.

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRIES ENTERPRISES)

The ASX says Palla Pharma will be removed from the Official list at the close of trading today, August 2, 2022.
Last year, Palla said it had entered voluntary administration with Korda Mentha appointed administrators (BD: Dec 17, 2021).
In February, Korda Mentha said it had been unable to find a buyer for the company, and would to 'wind-down' operations in Australia (BD: Feb 16, 2022).
In March, Korda Mentha said administrators "do not anticipate a return to shareholders" (BD: Mar 3, 2022).
Palla last traded at 29.5 cents.

CRESO PHARMA

Creso has requested an extension to its suspension, to follow its trading halt "pending an announcement in relation to a capital raising" (BD: Jul 29, 2022).
Yesterday, Creso said it had a non-binding agreement to acquire the Perth-based medical marijuana distributor Health House International for up to $4,630,388 in shares and options (BD: Aug 1, 2022).
Today, the company said trading will resume on August 4, 2022 or on an earlier announcement.
Creso last traded at 4.9 cents.

MEDADVISOR

Guild Group Holdings says it has become substantial in Medadvisor after it acquired 57,118,490 shares or 13 percent.
The Melbourne-based Guild Group said that on May 27, 2022, it received 57,118,490 shares for 100 percent of Guildlink, an associate of Guild Group.
Last month, the company 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 fell one cent or 5.9 percent to 16 cents.

MEDADVISOR

Regal Funds Management says it has reduced its holding and been diluted in Medadvisor from 30,787,747 shares (8.09%) to 30,605,090 shares (6.99%).
The Sydney-based Regal said that on July 27, 2022 it sold 182,657 shares for $28,442 or an average of 15.6 cents a share, and that it was diluted due to the release of 57,118,490 shares on the same date (see above).

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Boston's Life Biosciences says it has reduced its substantial holding in Alterity from 213,238,233 shares (8.9%) to 179,287,533 shares (7.5%).
In 2018, Life Biosciences invested $44.6 million in the then Prana, and in 2019 Prana shareholders voted to approve the Life Biosciences investment for 63 percent of the company and changed the name to Alterity (BD: Jan 20, Mar 6, 2019).
Today, the company said it sold American depositary shares, each equivalent to 60 Australian shares, between July 19 and August 1, 2022, with the single largest sale of 150,799 American depositary shares (equivalent to 9,047,940 Australian shares) for $US90,917 ($A130,567) or 60.29 US cents a share, equivalent to 1.44 cents per Australian share.
Alterity was unchanged at 1.6 cents with 3.7 million shares traded.

ARTRYA

Artrya says it has appointed Dr Jacque Sokolov as a US-based non-executive director, effective immediately.
Artrya said that Dr Sokolov was appointed to its clinical advisory board as chair in January and as chair and head of Artrya USA Inc in March 2022, and he had most recently worked as chair and chief executive officer of SSB Solutions.
The company said that Dr Sokolov was currently a director of Globalmed, Calviri and Lucid Diagnostics.
Artrya said Dr Sokolov held a Bachelor of Arts and Doctor of Medicine from the University of Southern California in Los Angeles.
Artrya fell two cents or 2.9 percent to 67 cents.

HEXIMA

Hexima says chief operating officer Nicole van der Weerden will replace managing-director Michael Aldridge as interim chief executive officer, effective immediately.
Hexima said Mr Aldridge would continue as a non-executive director, but would not receive remuneration for his role.
In June, the company fell 84.6 percent to four cents on news that its phase II study of pezadeftide (HXP124) for onychomycosis was "inconclusive ... [and did] not support moving directly into a phase III program" (BD: Jun 24, 2022).
Last month, Hexima dropped a further 48.15 percent on news that following the failure of HXP124 to show efficacy for nail fungus it had begun the process of winding-up activities (BD: Jul 11, 2022).
Hexima was unchanged at 1.1 cents with 2.1 million shares traded.

NYRADA

Nyrada says Noxopharm chief executive officer Dr Gisela Mautner will replace Peter Marks as a non-executive director, effective from August 1, 2022.

In January, Noxopharm said chief medical officer Dr Gisella Mautner would replace Dr Graham Kelly as chief executive officer and managing director (BD: Jan 16, 2022).

Today, Nyrada said Dr Mautner had previously worked for Merck Sharp and Dohme, Bayer and Amgen.

According to her Linkedin page, Dr Mautner held a Doctor of Medicine from the Technical University of Munich, a Doctor of Philosophy in Medicine, from Ludwig-Maximilians-Universität München, a Master of Business Administration from Kellogg-WHU in Mayen-Koblenz, Germany, and a Master of Public Health from Harvard University in Boston, Massachusetts.

Nyrada said Mr Marks had resigned “to pursue a range of other interests”.

Nyrada was up half a cent or 3.2 percent to 16 cents.

AUSBIOTECH

Ausbiotech says a steering group will lead the Cell and Gene Catalyst to develop, manufacture and distribute cell and gene therapies to Australian patients.

Ausbiotech said the group included Medicines Australia, CSL Behring, Novartis, Pfizer, Therapeutic Innovation Australia and Cell Therapies.

The industry organization said that the Cell and Gene Catalyst was a joint venture between it and Medicines Australia, which would focus on the ‘Regenerative Medicines in Australia: A Strategic Roadmap for the Regenerative Medicines Sector’ program, which could be found at: https://www.ausbiotech.org/documents/item/677.

Ausbiotech said that the Cell and Gene Catalyst would “discover, develop, manufacture and distribute cell and gene therapies to Australian patients, while creating jobs, commercializing research, and exporting Australian therapies to the world” and that it was supported by the Victorian Government’s Australian Medtech Manufacturing Centre.

The organization said it had begun recruitment processes for a two-year general-manager role, and that it had established a dedicated project manager for cell and gene therapy manufacturing.

Ausbiotech chief executive officer Lorraine Chiroiu said “Australia offers a wealth of opportunity in cell and gene therapies and the formation of the Cell and Gene Catalyst’s Steering Group is a powerful step towards realizing our national potential”.

Medicines Australia chief executive officer Elizabeth de Somer said “the Cell and Gene Catalyst is a timely initiative that will bring together global companies with Australian [small and medium-sized enterprises] to drive better healthcare outcomes and help build an Australian innovation-led economy fit for the 21st Century”.