Biotech Daily

Tuesday June 14, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: POLYNOVO UP 8%; PROTEOMICS DOWN 16%**

*** RESAPP: PFIZER INCREASES OFFER TO $125m - $178m**

*** PRO MEDICUS: $47m SUTTER, WELLSPAN RENEWALS**

*** VICTORIA $2m FOR mRNA, NOXOPHARM; $400k FOR MANUFACTURING**

*** OVENTUS 'VOLUNTARY ADMINISTRATION TO RESTRUCTURE'**

*** AUSBIOTECH 'SNAPSHOT' CLAIMS 43% INCREASE SINCE 2019**

*** TRAJAN 'NON-OPERATIONAL FACTORS' CAUSE 11% PROFIT WARNING**

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*** PATRYS PAT-DX1 'MIGHT REDUCE CANCER METASTASIS'**

*** ADALTA EUROPE PATENT FOR AD-214**

*** RADIOPHARM: ISOTOPIA TO SUPPLY LUTETIUM-177 NCA**

*** ZELIRA TERMINATES DRCN LICENCE, RECEIVES $360k**

*** CRESO: $15k 1st NEW MARIJUANA STRAINS ORDER**

*** MEDIBIO REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** EVERCORE, WILLIAM BLAIR CEASE IN BIONOMICS**

*** OPTISCAN APPOINTS ORCHID'S SEAN GARDNER DIRECTOR**

*** MEDIBIO DIRECTOR PETER CARLISLE MOVES TO ADVISER**

MARKET REPORT

The Australian stock market tumbled 3.55 percent on Tuesday June 14, 2022, with the ASX200 - following the US market - down 246.0 points to 6,686.0 points.

Just three of the Biotech Daily Top 40 stocks were up, 31 fell and six traded unchanged.

Polynovo was the best of the three, on one of the few days in recent weeks when chair David Williams did not disclose buying shares, up nine cents or 7.8 percent to $1.245, with 5.2 million shares traded. Next Science was up six percent; Cyclopharm rose 2.75 percent; with Resmed up by 0.2 percent.

Proteomics led the falls, down 14.5 cents or 16.4 percent to 74 cents, with 196,429 shares traded, followed by Prescient down 13.1 percent to 16.5 cents, with 4.7 million shares traded.

Mesoblast and Universal Biosensors lost more than 10 percent; Atomo, Immutep and Orthocell fell more than eight percent; Avita, Nova Eye and Pharmaxis were down seven percent or more; Antisense, Dimerix, Impedimed and Imugene were down more than six percent; Emvision, Pro Medicus and Starpharma were down more than five percent; Alcidion, Cochlear, Genetic Signatures, Medical Developments, Nanosonics, Oncosil, and Resonance fell four percent or more; Clinuvel, Micro-X, Neuren, Opthea and Paradigm were down more than three percent; Compumedics and CSL shed more than two percent; with Actinogen and Volpara both down 1.7 percent.

RESAPP HEALTH

Resapp says Pfizer Australia Holdings Pty has increased its offer to buy the company with a revised scheme consideration, offering up to $178 million.

Resapp said that Pfizer Australia agreed to increase the scheme consideration from 11.5 cents a share, valuing the company at about $100 million, to 20.7 cents a share on satisfaction of a confirmatory data readout condition, valuing it at about $178 million, or to 14.6 cents a share in the event the confirmatory data readout condition is not satisfied, valuing the company at about $125 million.

The company said that the revised scheme consideration followed negotiations with Pfizer after a draft independent expert report which determined that the value of a Resapp share was 14.6 to 27.7 cents, with a preferred value of 20.7 cents a share.

Resapp said that the draft independent expert report confirmed that the revised scheme was fair and reasonable, and in the best interest of Resapp shareholders.

Resapp said that the data confirmation study was being undertaken to confirm that its Covid-19 cough-based detection tool performed at or around the sensitivity and specificity reported in its pilot study (BD: Mar 22, 2022).

The company said the confirmatory data readout condition price of 20.7 cents a share was a 130.0 percent premium to the 9.0 cents a share closing price on April 8, 2022, with the 14.6 cents a share price a 62.2 percent premium to its April 8 closing price.

The company said its directors unanimously recommended that shareholders vote in favor of the revised scheme at the scheme meeting, expected in August 2022.

Resapp managing-director Tony Keating said that “the Resapp board is pleased to announce the renegotiated agreement with Pfizer which represents a material increase in the consideration to be received”.

Resapp was up 5.5 cents or 50 percent to 16.5 cents with 8.0 million shares traded.

PRO MEDICUS

Pro Medicus says it has two contract renewals worth a combined $47 million with the Sacramento, California-based Sutter Health and York, Pennsylvania's Wellspan Health.
The company said it had contracts for an additional seven years with Sutter and an additional five years with Wellspan, and both were negotiated at a higher per transaction cost than previously, with committed minimums.
Pro Medicus chief executive officer Dr Sam Hupert said that "the industry norm for renewals is for short extensions to the original contract at the same or lower price".
"The fact that our clients have renewed for a full or longer contract term at an increased price supports our belief that the Visage solution delivers unparalleled value both in terms of financial and clinical [return on investment]," Dr Hupert said. "Whilst it is still early days, our renewal success rate sends a positive message to the market and helps build on the network effect that we have been experiencing."
Pro Medicus fell $2.27 or 5.5 percent to $39.11 with 444,883 shares traded.

VICTORIA GOVERNMENT

The Victoria Government says it has provided $2 million for 12 mRNA research projects and $400,000 for two innovation challenges to develop healthcare products.
The Victoria Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said the first round of recipients from the mRNA Victorian Research Acceleration Fund included a research partnership between Monash University and Alfred Health to develop a liptotide-based nanoparticle RNA delivery technology for muscular dystrophy.
The Government said the Florey Institute of Neuroscience and Mental Health would partner with Monash University to develop an mRNA vaccine for Alzheimer's disease.
A media release from Ms Pulford said the grants were part of the $50 million commitment to establish an mRNA industry by supporting projects developing artificial intelligence technology, next generation manufacturing, safety testing and alternative vaccine delivery.
In a separate announcement, Noxopharm said that $100,000 from the mRNA Fund would go to the Monash University-based Hudson Institute of Medical Research for a study into RNA-based therapeutics; and its subsidiary Pharmorage Pty Ltd was collaborating with the Hudson Institute and the Australian National University in Canberra on a project to explore TLR7-driven autoimmune disease.
Noxopharm said it would match the grant, "with a view to progressing promising drug candidates into the Noxopharm drug development program, under the terms of its licence agreement with Hudson Institute" and if the technology was proven, it would investigate the development of further oligonucleotide drug candidates with potential indications in other autoimmune diseases and the project would begin shortly and run for 12 months.
In a separate announcement, Ms Pulford announced $400,000 for two innovation challenges to fast-track the development of healthcare products.
The media release said the Aikenhead Centre for Medical Discovery Medtech Challenge and the Swinburne Livingat Health Innovation Challenge would "strengthen ties between allied health workers, researchers, developers and manufacturers".
The State Government said the Aikenhead Challenge would "focus on creating special equipment to assist people with conditions including type 2 diabetes, osteo-arthritis and neurological conditions such as epilepsy", with the Swinburne Challenge hoping to develop customized designs for new mobility aids, such as wheelchairs and walkers.
The State Government said that the programs were funded by the Australian Medtech Manufacturing Centre and for more information, go to: https://bit.ly/3OdgT6V.
Noxopharm fell two cents or 8.3 percent to 22 cents with 1.4 million shares traded.

OVENTUS

Oventus says it has appointed Grant Thornton's Michael McCann and Graham Killer of Grant Thornton as voluntary administrations.

Oventus said that the Grant Thornton insolvency firm would review and assess its operations and might look to undertake a sale or recapitalization process during the administration period, with an initial meeting to be held within eight days.

The company said it would work with the voluntary administrators to "maximise the outcome for all stakeholders of the company".

Oventus said that while in administration it would remain suspended, with shareholders unable to transfer their shares during the suspension.

Oventus last traded at two cents.

AUSBIOTECH

Ausbiotech says that its Sector Snapshot shows the Australian biotechnology sector has increased 43 percent since 2019 and 60 percent since 2017.

Ausbiotech said that 1,427 of the 2,654 biotechnology organizations (54 percent) were industry-based, with the number of companies undertaking research and development increasing by 40 percent since 2019.

The industry organization said that there were 192 life sciences companies listed on the ASX, a 19 percent increase from 161 in 2019.

Biotech Daily covers about 140 companies that are involved in the development of drugs devices and diagnostics for human health, while Ausbiotech uses a broader definition.

Ausbiotech said that the ASX-listed biotechnology companies had a collective market capitalization of about $233 billion compared to about $170 billion in 2019.

Biotech Daily reported that at May 31, 2021, the three Big Caps of Cochlear, CSL and Resmed (which are not included in the Biotech Daily Top 40 Index – BDI-40) had a collective market capitalization of $188.3 billion with the BDI-40 comprising a further $14.2 billion, and the remaining 100 companies totalling $7.6 billion, for a total of $210.1 billion (BD: Jun 1, 2022).

Ausbiotech said that the cumulative market capitalization was "one quantifiable measure of the life science sector's contribution to the Australian economy".

The industry organization said that the proportion of biotech companies achieving market valuations greater than $100 million "measures the industry's ability to create companies of significant future value".

Ausbiotech said that the number of employees increased 21 percent from 2019 to more than 105,000 staff in 2022.

Ausbiotech chief executive officer Lorraine Chiroiu said the Snapshot "recognises the sovereign value of our Australian biotechnology sector, and its place as a significant economic and social driver for our country".

"The substantial strength of the life sciences sector, shown in the sector Snapshot 2022 through the substantially increasing numbers of organizations and the people employed within it, depicts an actively thriving ecosystem," Ms Chiroiu said.

"This maturity is a key factor for the industry's ability to attract and retain high-value jobs and backs its ability to compete on the world stage in a knowledge-based economy," Ms Chiroiu said.

The Snapshot is available at: https://www.ausbiotech.org/documents/item/707.

TRAJAN GROUP HOLDINGS

Trajan says it has reduced its earnings guidance from between $12.5 million to $13.5 million, to a range of $11.2 million to $12.0 million, for the year to June 30, 2022.
Trajan said that delays would cause $1.7 million in revenue to be re-timed and recognized in its 2023 financial year and that it had an estimated $800,000 devaluation of future hedging contracts.
The company said these two “non-operational” factors had a combined $1.6 million impact on earnings before interest, taxation, depreciation and amortization (Ebitda) bringing the midpoint down from $13.0 million to $11.6 million, a decrease of 10.77 percent.
Trajan said that the non-operational factors did not reflect weaknesses in its business.
Trajan fell 19 cents or 7.6 percent to $2.30.

MESOBLAST

Mesoblast says it will “vigorously defend” a second class action filed by law firm Phi Finney McDonald in the Federal Court of Australia.
Last month, Mesoblast said it had been served a class action in the Federal Court of Australia by William Roberts Lawyers on behalf of certain shareholders who acquired an interest in the company’s shares, American depository receipts, or related equity swap arrangements between February 22, 2018 and December 17, 2020 (BD: May 19, 2022).
At that time, the company said it had settled a similar suit in the US for $2 million with no admission of liability, and that the settlement sum, minus the minimum excess associated with the company’s insurance, had been paid by the Mesoblast’s insurer, but did not specify the currency.
Last year, at least four US law firms began class actions against Mesoblast claiming that the company failed to inform investors of the risk of graft-versus-host disease success (BD: Oct 21, 2021).
Today, Mesoblast said that the US court granted preliminary approval of the settlement on April 8, 2022 and had scheduled a final approval hearing for August 15, 2022.
The company said the Phi Finney McDonald served the second class action in the Federal Court of Australia “canvassing similar allegations” to those from William Roberts Lawyers.
On its website, Phi Finney McDonald said the class action was in relation to Mesoblast’s statements to the market regarding the potential application of its Remestemcel-L product for children with steroid refractory acute graft versus host disease and patients with acute respiratory distress syndrome caused by Covid-19 and alleged that “Mesoblast breached its continuous disclosure obligations, and engaged in misleading and deceptive conduct: in relation to announcing trial results.
Mesoblast said that it would “vigorously defend both proceedings”.
Mesoblast fell eight cents or 10.3 percent to 70 cents with 4.1 million shares traded.

MICRO-X

Micro-X says it has a $1 million US distribution agreement for its Rover mobile x-ray system with the Pinebrook, New Jersey-based Medlink Imaging.
Micro-X said the three-year agreement had a one-year automatic renewal term and an initial commitment of $1 million to acquire Rover mobile systems during the first year and each year after, following regulatory approvals expected by December 2022.
The company said that Medlink was a subsidiary of the Anyang, South Korea-based Vieworks and that the agreement added 100 sub-distributors to its network.
Micro-X fell half a cents or 3.2 percent to 15 cents with 1.5 million shares traded.

OSTEOPORE

Osteopore says it has expanded into Africa with its first shipment of cranial regenerative implants to Chronos Medical in Johannesburg, South Africa.
Osteopore said its implants had been approved by the South African Health Products Regulatory Authority but initial sales were not material in terms of revenue.
Osteopore executive chair Mark Leong said that first sales in South Africa was “a fantastic milestone … and is evidence of the team’s execution ability to open new markets”.
“Our regenerative implants are now sold in every continent,” Mr Leong said.
Osteopore was unchanged at 14 cents.

ADHERIUM

Adherium says it has a three-year, UK distribution agreement for its Hailie sensors and cloud data services with London’s Helicon Health.
The company did not disclose the commercial terms of the agreement.
Adherium head of business development Francis White said that “this agreement with Helicon presents a significant opportunity to better serve the often-overlooked severe asthma population and give a true and metric driven care pathway for [chronic obstructive pulmonary disease] patients”.
“The expertise of the team at Helicon will transform our market access in the UK, give us opportunities in ground-breaking care and accelerate adoption,” Mr White said.
Adherium was unchanged at 0.7 cents with 3.1 million shares traded.

ACTINOGEN MEDICAL

Actinogen has detailed its plans for two phase II trials of Xanamem for Alzheimer’s disease and major depressive disorder.
Actinogen said that the phase II trials followed its 107 healthy adult phase Ib, ‘Xanamia’ study of Xanamen for cognition, which met its primary safety, pharmacodynamic and efficacy endpoints (BD: Apr 27, 2022).
The company said that its 300-patient, Alzheimer’s disease, phase II trial would be a six-month, dose-ranging, placebo-controlled study of the effects of 5mg and 10mg Xanamem on cognition, with results expected in 2024.
Actinogen said that patients in the Alzheimer’s study would include people with early stages of Alzheimer’s disease, patients with mild cognitive impairment and patients with mild Alzheimer’s disease.
The company said that its 120-patient, major depressive disorder, phase II trial would be a six-week, proof-of-concept, placebo-controlled study of 10mg Xanamem daily or placebo, in addition to anti-depressant therapy, to test the effects on both depression and cognition, with results expected in late 2023 or 2024.
The company said the trial would include patients with persistent major depressive disorder and cognitive difficulties despite a standard course of anti-depressant therapy.
Actinogen chief executive officer Dr Steven Gourlay said the results from the recent Xanamia trial were “exciting and highly confirmatory”.
“We are now initiating two robust phase II trials in patients with Alzheimer’s disease and depression,” Dr Gourlay said.
“Xanamem has the potential to be an effective low-dose daily oral therapy for these and many conditions where it may be used alone or in combination with other treatments,” Dr Gourlay said.
Actinogen fell 0.1 cents or 1.7 percent to 5.9 cents with 2.9 million shares traded.

KAZIA THERAPEUTICS

Kazia says that data presented at the Symposium on Paediatric Neuro-oncology in Germany shows benefits of ONC201 and paxalisib in childhood brain cancer.

Kazia said that the Symposium was held in Hamburg, Germany from June 12 to 15, 2022 and that the data was the subject of two poster presentations.

The company said that the first poster, titled 'The PI3K inhibitor paxalisib, combined with the novel HDAC1/3 inhibitor RG2833, may improve survival in mice bearing orthotopic xenografts of atypical teratoid/rhabdoid tumors', was presented by Dr Jeffrey Rubens the Baltimore, Maryland-based John Hopkins University.

Kazia said that the second abstract, titled 'Preclinical and case study results underpinning the phase II clinical trial testing the combination of ONC201 and paxalisib for the treatment of patients with diffuse midline glioma', was presented by Dr Matt Dun from the Hunter Medical Research Institute at the University of Newcastle.

The company said that two patients who received the combination of the Durham, North Carolina-based Chimerix Inc's ONC201 and paxalisib under compassionate access showed "dramatic reductions in tumor volume and complete resolution of disease symptoms, extending overall survival".

Kazia chief executive officer Dr James Garner said that "Dr Dun's painstaking research over several years has yielded enormous insight into potential treatments for [diffuse intrinsic pontine glioma]".

"We are excited to see such an emphatic demonstration of the potential for ONC201 and paxalisib to provide benefit in this disease … [and] we are firmly committed to taking paxalisib forward in childhood brain cancer, and very much hope that the work of world-leading scientists such as Dr Dun will help to bring hope to all those touched by diseases such as for [diffuse intrinsic pontine glioma]," Dr Garner said.

Kazia was unchanged at 78 cents.

CYNATA THERAPEUTICS

Cynata says that its Cymerus mesenchymal stem cells for idiopathic pulmonary fibrosis shows "highly potent anti-inflammatory effects", in mice.

Cynata said the study was conducted by the Melbourne-based Monash University's Prof Chrishan Samuel and was in mice subjected to bleomycin-induced pulmonary fibrosis which "mimics features of idiopathic pulmonary fibrosis in humans".

The company said that Cymerus mesenchymal stem cells were dosed, either once or once-weekly over two weeks and compared with saline controls with six to 10 mice in each group.

Cynata said the treated mice showed significant amelioration of the bleomycin-induced macrophage, dendritic cell and T-cell influx into the airways and lungs, significantly promoted anti-inflammation levels in airways and lungs, and significantly reduced the bleomycin-induced interstitial collagen area, among other effects.

Cynata chief operating officer Dr Kilian Kelly said the study provided "extensive detail around the molecular mechanisms associated with the observed high potency of Cynata's proprietary Cymerus mesenchymal stem cells".

"The results provide additional data in support of investigating the clinical utility of our MSCs in fibrotic diseases of the lungs and potentially of other organs, a pathway we are seeking to pursue with potential commercial partners," Dr Kelly said.

Cynata was unchanged at 37 cents.

PATRYS

Patrys says a range of in-vitro studies show that its PAT-DX1 deoxymabs can “potentially treat metastatic cancer, as well as certain inflammatory diseases”.
Patrys said that a peer-reviewed article, titled ‘Inhibition of NETosis by a nuclear penetrating anti-DNA autoantibody’, by Yale Universoty’s Dr James Hansen and Monash University’s Dr Kim O’Sullivan was published in Immunohorizons, with the full article available at: https://www.immunohorizons.org/content/6/6/356.
The company said the studies showed that PAT-DX1 suppressed the formation of neutrophil extracellular traps in neutrophil cells, which “may play an important role in the establishment and maintenance of cancer cells, cancer spreading, and regulating inflammation”.
Patrys managing-director Dr James Campbell said that “this is an unexpected and important discovery for Patrys, offering mechanistic rationale to the previously-described ability of PAT-DX1 to reduce cancer spread by metastasis and opening the door to broader uses of deoxymabs in non-cancer indications, particularly chronic inflammatory conditions that are driven by [neutrophil extracellular trap] formation”.
“The discovery has been protected by patent application, and opens new areas for business development to Patrys,” Dr Campbell said.
Patrys was unchanged at two cents with 4.8 million shares traded.

ADALTA

Adalta says the European Patent Office has granted a patent for the “i-body” sequence in AD-214, pharmaceutical compositions and derivatives containing the sequences.
Adalta has previously said that i-bodies were named from the “intermediate” of four groups of immunoglobulin or immunoglobulin-like domains.
Today, the company said that the patent, titled ‘CXCR4 binding molecules’, would protect its intellectual property until January 8, 2036.
Adalta said that its i-body technology mimicked the shape and stability of a unique and versatile antigen binding domain, developed as a human protein to target receptors implicated in many serious diseases.
The company said that the patent protected the use of the sequences in therapeutic and diagnostic applications, including idiopathic pulmonary fibrosis, the lead indication for which AD-214 was being developed.
Adalta was up 0.2 cents or four percent to 5.2 cents.

RADIOPHARM THERANOSTICS

Radiopharm says Isotopia Molecular Imaging will supply it with Lutetium-177 no carrier added (NCA) for research, development, manufacture and commercialization.
The company said that the Tel Aviv-based Isotopia’s Lutetium-177 NCA was a key isotope required for its clinical trials and would help it in the early-stage commercialization of its diagnostic and therapeutic products.
Radiopharm managing-director Riccardo Canevari said that “radiopharmaceutical therapies represent the new frontier in oncology and significant growth is expected over the next five to 10 years, when you can combine the right molecule with the right isotope in areas of high unmet medical needs”.
“Access to high quality Lutetium-177, in its high purity version - non-carrier added - allows us to more quickly progress broad pipeline,” Mr Canevari said.
Radiopharm fell three cents or 17.1 percent to 14.5 cents.

ZELIRA (FORMERLY ZELDA) THERAPEUTICS

Zelira says it has terminated its technology licence with Delarawre's DRCN Holdings LLC for its matrix-based cannabinoid capsules but received $US250,000 ($A359,586).
In April, Zelira said $US750,000 in licencing fees were overdue from DRCN and it was considering legal options, including termination (BD: Apr 6, 2022).
Today, Zelira said it had received$US500,000 in upfront, non-refundable fees from DRCN and DRCN did not receive or gain access to any aspect of its technology.
Zelira fell 15 cents or 13.0 percent to $1.00.

CRESO PHARMA

Creso says its Windsor, Nova Scotia-based, subsidiary Mernova Medicinal, has received orders worth about $CA13,68 ($A15,291) for new marijuana strains.
Creso said that the new strains, called Mac 1 and Grape Cream Cake, were in a 3.5-gram dried flower format and were ordered from the province of Saskatchewan.
Creso fell 0.3 cents or 6.25 percent to 4.5 cents with 7.7 million shares traded.

MEDIBIO

Medibio says it has requested a trading halt pending the release of an announcement "regarding a capital raising".
Trading is expected to commence on June 16, 2022 or on an earlier announcement.
Medibio last traded at 0.3 cents.

BIONOMICS

New York's Evercore Group LLC and Chicago's William Blair & C said they both ceased their substantial holdings in Bionomics following the end of lock up agreements.
Last year, Bionomics said it raised about $US20 million ($A28 million) in an initial offering of 1,622,000 American depositary shares on the Nasdaq (BD: Jan 16, 2022).
Bionomics fell 0.1 cents or 1.8 percent to 5.5 cents.

OPTISCAN IMAGING

Optiscan says it has appointed Sean Gardiner as a non-executive director, as nominated by Orchid Capital Investments, in their subscription agreement.
Optiscan said that Mr Gardiner was a managing-director and head of private investments at the Clermont Group, previously worked at Morgan Stanley and held a Bachelor of Commerce from the University of Cape Town in South Africa.
Optiscan was up half a cent or four percent to 13 cents.

MEDIBIO

Medibio says Peter Carlisle has resigned as non-executive director, effective from June 10, 2022 and would join the growth and advocacy advisory board.