Biotech Daily

Wednesday July 26, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: KAZIA UP 8%; STARPHARMA DOWN 14%**

*** SOMNOMED RECEIPTS UP 15% TO $82.5m**

*** LBT RECEIPTS UP 8-FOLD TO $3.8m**

*** ANTEOTECH RAISES $4m, PLAN FOR $2m MORE**

*** CLINUVEL US VETERAN AFFAIRS SCENESSE FOR EPP CONTRACT**

*** HAEMALOGIX, PETER MAC TRIAL KMA.CAR-T FOR MULTIPLE MYELOMA**

*** NSW GOVERNMENT $994k FOR CENTENARY HEART RESEARCH**

*** NSW GOVERNMENT $500k FOR NSW UNI CHEMO BRAIN IMPACT**

*** BURNET WINS ISO 9001**

*** BIOCURATE PARTNERS WITH SINGAPORE DRUG DEVELOPMENT CENTRE**

*** CLARITY STARTS CU-67-SARTATE NEURO-BLASTOMA FINAL COHORT**

*** ALTERITY: DMC OKAYS ATH434 MSA TRIAL**

*** STARPHARMA JOINS QUEENSLAND UNI RADIO-PHARMACEUTICALS**

*** ANTISENSE: ATL1102 COMBO 'IMPROVES MUSCLES, STRENGTH, IN MICE'**

*** VITURA: W.H.O. GRANTS 'GOOD-DISTRIBUTION PRACTICE'**

*** INCANNEX FDA IHL-675A MARIJUANA ARTHRITIS IND MEETING**

*** LIVING CELL FILES AI-116 MARIJUANA COMBO FOR DEMENTIA PATENT**

*** CARDIEX TO LIST NASDAQ AMERICAN DEPOSITARY SHARES**

*** MEDICAL DEVELOPMENTS PLEADS SCHULTZ TO ASX 29% FALL QUERY**

*** VIBURNUM FUNDS TAKES 7.5% OF MAYNE PHARMA**

*** PLATINUM TAKES 13.3% OF ANTISENSE**

*** FUJIFILM BELOW 5% IN CYNATA**

*** REGAL DILUTED TO 13% OF IDT**

MARKET REPORT

The Australian stock market was up 0.85 percent on Wednesday July 26, 2023, with the ASX200 up 62.3 points to 7,402.0 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and one was untraded.

Kazia was the best, up one cent or eight percent to 13.5 cents, with 30,439 shares traded.

Orthocell climbed 5.5 percent; Micro-X improved 4.2 percent; Universal Biosensors rose 2.1 percent; Antisense, Clinuvel, Emvision, Immutep and SDI were up more than one percent; with Cochlear, Cyclopharm, Genetic Signatures, Opthea, Polynovo, Pro Medicus and Resmed up by less than one percent.

Starpharma led the falls, down five cents or 13.9 percent to 31 cents, with 1.35 million shares traded.

Medical Developments and Resonance lost more than seven percent; Atomo shed 6.25 percent; Pharmaxis was down 5.2 percent; Impedimed fell 4.65 percent; Avita, Imugene and Prescient were down more than three percent; Actinogen, Neuren and Volpara shed more than two percent; CSL, Dimerix, Mesoblast, Next Science, Nova Eye, Paradigm, Proteomics and Telix were down one percent or more; with 4D Medical down by less than one percent.

SOMNOMED

Somnomed says receipts from customers for the year to June 30, 2023 were up 15.4 percent to $82,497,000, compared to the previous corresponding period.
Somnomed said receipts from sales of its sleep apnoea oral appliance for the three months to June 30, 2023 were up 10.35 percent to $21,884,000, compared to the previous corresponding period.
The company said it was cash flow positive by $2,536,000 for the three months to June 30, 2023, with cash and cash equivalents of $11,956,000, compared to $15,644,000 the previous year.
Somnomed fell four cents or 3.9 percent to 99 cents.

LBT INNOVATIONS

LBT says receipts from customers for the year to June 30, 2023 were up 717.85 percent to $3,803,000 compared to the previous corresponding period.
LBT said receipts from customers for the three months for sales of its Apas (automated plate assessment system) to June 30, 2023 were up 2,341.7 percent to $586,000 compared to the previous corresponding period.
The company said it had a cash burn of $872,000 for the three months to June 30, 2023 and cash and cash equivalents of $2,020,000, compared to $2,788,000 the previous year, providing funding for 2.3 quarters.
LBT fell 0.3 cents or 12.5 percent to 2.1 cents.

ANTEOTECH

Anteotech says it has commitments to raise $4.0 million through a placement at 3.2 cents a share and hopes to raise $2.0 million through a share plan.
Anteotech said investors would receive one option for every two shares acquired, exercisable at 6.4 cents within three years.
The company said the share price was a 17.9 percent discount to the July 21, 2023 closing price and a 22.8 percent discount to the 15-day volume weighted average price.
Anteotech said the share plan had a record date of July 25, would open on August 8 and close on August 23, 2023.
The company said it would use the funds to further sales and marketing for its Anteo X high silicon anodes, test and commercialize the anodes, and commission a 20,000-litre annual capacity production facility and expand it to 80,000 litre capacity.
Anteotech said Canaccord Genuity (Australia) was the sole lead manager for the placement and Fosters Stockbroking was co-manager, with Hawkesbury Partners as financial advisers.
Anteotech fell 0.6 cents or 15.4 percent to 3.3 cents with 9.6 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will supply the US Department of Veterans Affairs with Scenesse for adult erythropoietic protoporphyria patients (EPP) for five years.
Clinuvel said the Federal Supply Schedule authorized about 400 companies to supply pharmaceuticals to the US Department of Veterans Affairs, with about 1,300 Veterans Affairs healthcare facilities in the US.
The company said that the listing enabled any adult EPP patient covered by the Veterans Affairs health care program to receive Scenesse at all facilities until July 2028, when the contract could be reviewed and renewed.
Clinuvel said that about nine million individuals were enrolled in the Veterans program,
The company did not disclose commercial terms of the deal.
Clinuvel was up 35 cents or 1.9 percent to $18.77 with 99,126 shares traded.

HAEMALOGIX, PETER MACCALLUM CANCER CENTRE.

Haemalogix says it will codevelop and conduct a six to 12 patient proof-of-concept trial of its KMA.Car-T for kappa-type multiple myeloma at the Peter MacCallum Cancer Centre.
Sydney's Haemalogix said that KMA.Car-T was a chimeric antigen receptor T (Car-T)- cell therapy for patients with kappa-type multiple myeloma and the agreement with Melbourne's Peter MacCallum Cancer Centre was "the culmination of previous pre-clinical research … between the two teams, which demonstrated compelling proof of concept".
The company said that the phase I trial aimed to show the clinical safety and efficacy of KMA.CAR-T in a limited number of patients, initially six patients, with the possibility of expanding to 12 patients.
Haemalogix said that KMA.Car-T targeted the Kappa myeloma antigen receptor (KMA) found only on the surface of myeloma cells in kappa-type multiple myeloma patients and not on normal immune cells, which meant that normal immune cells were not damaged by the treatment.
Haemalogix director and chief scientific officer Dr Rosanne Dunn said that "Car-T cell therapy was "a realistic option for myeloma patients who have failed standard of care treatments".
Haemalogix is a public unlisted company.

CENTENARY INSTITUTE, NEW SOUTH WALES GOVERNMENT

The Centenary Institute says the State Government has provided $994,000 to research the Krüppel-like factor-1 protein stimulate the growth of heart muscle cells.
The Centenary Institute said that the New South Wales Government Cardiovascular Collaborative Grant had been awarded to Dr Daniel Hesselson under the Government's Cardiovascular Research Capacity Program.
The Institute said that heart muscle damage resulting from a heart attack or heart muscle disease could lead to reduced heart function and life expectancy as well as decreased quality of life.
The Centenary Institute said Dr Hesselson's research aimed to address the issue by enhancing the potency of the Krüppel-like factor-1 (KLF1) protein to stimulate the growth of heart muscle cells, to improve outcomes, wellbeing and survival of heart patients.
Dr Hesselson said that KLF1 was able to renew heart tissue in zebrafish but it didn't work the same way in humans.
"We hope to be able to use the technique of directed evolution to be able to 'evolve' KLF1 so that it can also work with people and potentially regenerate their heart muscle," he said.

UNIVERSITY OF NEW SOUTH WALES, NEW SOUTH WALES GOVERNMENT

The University of New South Wales says the State Government has granted nearly $500,000 to research gut-brain health affected by chemotherapy in young adults.
The University said that Dr Caitlin Cowan would lead the research in testing brain function and psychological well-being in patients and healthy adolescents and young adults using questionnaires and standardized tests of attention, learning and memory.
"We will then analyse blood and stool samples to identify markers related to symptoms," Dr Cowan said. "We will also use these samples in laboratory models to better understand whether gut bacteria can cause the symptoms … [and] we will ask young people about their experiences so that we can eventually develop useful treatments to reduce the impact of cancer therapy on the brain."
"We're trying to understand cognitive impacts of chemotherapy … in young people, which are pretty understudied, despite the fact that cognitive issues can be more problematic during that stage of life," Dr Cowan said.

BURNET INSTITUTE

The Burnet Institute says its Diagnostics Initiative has been awarded ISO 9001 certification, a major milestone aiding translational research.
The Burnet Institute said that the International Organization for Standardization (ISO) 9001 certification was "based on a number of quality management principles including a strong client focus, the motivation and implication of top management, the process approach and a commitment to continual improvement".
The Burnet Diagnostics Initiative director Jennifer Barnes said the external audit ensured the correct processes and frameworks were in place to monitor and track research and ensure it met quality standards.
"The certification gives our industry partners, funders and study participants confidence that we conduct our research in an ethical, robust and reproducible way that meets the highest international standards," Ms Barnes said.
Burnet Institute director Prof Brendan Crabb said the certification further strengthened the Institute's reputation as a place to do translational research.

BIOCURATE

Biocurate says it will share scientific and business development with Singapore's Experimental Drug Development Centre and explore co-development on projects.
Biocurate said that the Centre was Singapore's "national platform for drug discovery and development" hosted by the Agency for Science, Technology and Research (Astar).
Biocurate said that the Experimental Drug Development Centre had "well-established capabilities in-house for the discovery and development of small and large molecule therapeutic compounds" including expertise in assay development, medicinal chemistry, peptide chemistry, therapeutic protein and antibody discovery, in-vivo pharmacology and biomarker development.
Biocurate chair John Brumby said that "bringing new drugs to market is notoriously difficult and requires substantial scientific and commercial expertise and resources".
"Collaborations like this improve the prospects of success, and we are honored to partner with EDDC toward this common goal," Mr Brumby said.

CLARITY PHARMACEUTICALS

Clarity says it has completed dosing the penultimate third cohort of its US phase II trial of its 67-copper Sartate therapy for paediatric neuroblastoma.
Clarity said its safety review committee recommended the trial continue with dose escalation as planned, with recruitment of the final cohort open at trial sites in the US.
The company said the fourth cohort would escalate the 67-copper Sartate dose from 275 mega-Becquerel per kilogram (MBq/kg) to 375MBq/kg.
Clarity said some participants in previous cohorts had received additional therapy cycles, contingent on investigators' assessment that the participant showed therapeutic benefit after the first dose.
Clarity chief executive officer Dr Alan Taylor said the company was "excited to have reached this final cohort four in the CL04 trial."
"Neuroblastoma is one of the most aggressive childhood cancers and Clarity is dedicated to advancing the trial and exploring the diagnostic and therapeutic benefits of the Sartate products in these affected children, where no other treatment options are available," Dr Taylor said.
"In the cohort expansion phase, we will enrol an additional 10 subjects who will receive at least two therapy cycles of copper-67-Sartate at the highest dose determined by the escalation phase, with up to four therapy cycles in total for those participants who demonstrate therapeutic benefit," Dr Taylor said.
Clarity was up 1.5 cents or 1.7 percent to 89 cents.

ALTERITY THERAPEUTICS

Alterity says its data monitoring committee has recommended its up-to 60 patient phase II trial of ATH434-201 for early-stage multiple system atrophy continue unchanged.
In 2021, Alterity said it had New Zealand approval for the randomized, double-blind, controlled, phase II trial of ATH434 for multiple system atrophy (BD: Dec 14, 2021).
The company said the committee reviewed unblinded clinical data from a cohort of study participants and "expressed no concerns about safety".
Alterity said the trial was evaluating ATH434-201's effect on neuro-imaging and protein biomarkers to demonstrate efficacy, in addition to assessing safety and pharmacokinetics in the Parkinson's disease-related multiple system atrophy.
Alterity was up 0.1 cents or 14.3 percent to 0.8 cents with 4.5 million shares traded.

STARPHARMA HOLDINGS

Starpharma says it will collaborate with the University of Queensland to manufacture targeted radio-pharmaceuticals.

Starpharma said the University of Queensland's Hub for Advanced Manufacture of Targeted Radiopharmaceuticals (Amtar Hub) had been awarded $4.8 million from the Federal Government's Australian Research Council.

Last week, the company said its diagnostic dendrimer enhanced product (DEP) human epidermal growth factor receptor 2 (HER2)-zirconium had shown "improved sensitivity" for HER2-positive breast cancer in mice (BD: Jul 21, 2023).

Today, Starpharma said other partners included the Commonwealth Scientific and Industrial Research Organisation (CSIRO), Telix Pharmaceuticals and Clarity Pharmaceuticals.

Starpharma chief executive officer Dr Jackie Fairley said the company was "excited to collaborate with lead organization University of Queensland as part of the Amtar Hub to access additional resources and accelerate the development of our expanding portfolio of targeted DEP radio [diagnostic and therapeutic] products".

"The Amtar Hub is a significant initiative that will shape the future of Australia's radio [diagnostic and therapeutic] industry," Dr Fairley said.

Starpharma fell five cents or 13.9 percent to 31 cents with 1.35 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says ATL1102 combined with a dystrophin exon skipping restoration agent improved muscle damage and strength compared to the agent alone in mice.

In February, Antisense said a mouse study combining an antisense oligo-nucleotide targeting CD49d with a dystrophin exon skipping restoration (DSER) drug improved muscle function (BD: Feb 1, 2023).

Today the company said that to understand the mechanism behind the improved muscle strength, it tested the quadricep thigh muscle for muscle dystrophin protein levels, the dystrophin fluorescence intensity in the fibres and changes in cellular markers.

Antisense said antisense oligonucleotide targeting CD49d in combination with a DSER agent, as well as the sole DSER agent, demonstrated less than one percent of dystrophin protein levels in mice.

The company said that, typically, dystrophin protein levels in ambulant boys with Duchenne muscular dystrophy dosed with dystrophin restoration drugs Eteplirsen and Golodirsen were 0.44 percent and one percent respectively at 48 weeks.

Antisense said that, even with low levels of dystrophin protein, the dosed mice still had improved muscle function after receiving the Antisense oligo-nucleotide and DSER combination compared to the DSER agent.

Antisense director of drug discovery and patents Dr George Tachas said "the quadricep muscle is known to become rapidly weaker as children with Duchenne muscular dystrophy age, causing loss of ambulation, and whilst corticosteroid treatment prolongs ambulation for two to three years, better treatments are needed."

"These study results are exciting and suggest the potential for ATL1102 in combination with dystrophin restoration drugs to improve therapeutic outcomes in DMD patients," Dr Tachas said.

Antisense was up 0.1 cents or 1.85 percent to 5.5 cents with 1.9 million shares traded.

VITURA HEALTH

Vitura says the World Health Organisation has granted its Gold Coast, Queensland and Melbourne distribution centres “good distribution practice”.
Vitura said good distribution practice was a quality system for warehouse and distribution centres dedicated for medicines that considered issues like storage and handling.
In addition to the good distribution practice designation, the company said Cotrexa, its joint venture with Pharmala Biotech Holdings, had hired a medical business development manager and placed an order for good-manufacturing-practice-grade 3,4 methylene-dioxy-meth-amphetamine or MDMA.
Vitura was up one cent or two percent to 50 cents.

INCANNEX

Incannex says it has had a “constructive” pre-investigational new drug application meeting with the US Food and Drug Administration for IHL-675A for arthritis.
Incannex said IHL-675A contained cannabidiol (CBD) and hydroxychloroquine sulphate and it planned to use it to treat inflammatory diseases including rheumatoid arthritis, and had submitted a pre-investigational new drug application to the FDA in June 2023.
The company said it would incorporate the FDA’s “valuable multi-disciplinary feedback” into its clinical trial designs and overarching strategy for IHL-675A’s development.
Incannex was unchanged at 10.5 cents with 1.4 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says it has filed a provisional patent for a marijuana-based combination drug AI-116 for the treatment of dementia.
In 2015, Living Cell said that its Diabecell encapsulated pig islets of Langerhans cells for type one diabetes produced inconclusive results (BD: Nov 16, 2015).
Last year the company said it had raised $1.285 million in a placement at 0.5 cents a share to support its trial of NTCell encapsulated pig choroid brain cells for Parkinson’s disease (BD: May 31, 2022).
Today, the company said it was in discussions with an unnamed “major Australian university to conduct pre-clinical studies to assess AI-116, including comparing the efficacy of AI-116 to an existing class of drugs used to treat dementia”.
Living Cell did not respond to a request from Biotech Daily for the jurisdiction of filing, the patent title, or expected duration, should the patent be granted.
Living Cell was unchanged at 1.6 cents with 1.7 million shares traded.

CARDIEX

Cardiex says it has filed a registration statement with the US Securities and Exchange Commission for an initial public offering of American depositary shares (ADSs) on the Nasdaq.
Cardiex said that the number of ADSs to be sold, the issue price and the number of shares represented by each ADS had not yet been determined.
The company said the offering was subject to shareholder approval, which it would seek at an extraordinary general meeting.
Cardiex said Roth Capital Partners would be the lead book-running manager for the offering and that it would list the ADSs under the code CDEX.
Cardiex was up three cents or 18.2 percent to 19.5 cents with one million shares traded.

MEDICAL DEVELOPMENTS

Medical Developments has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price fell 29.2 percent from $1.68 a share on Tuesday July 25 to $1.19 and noted a "significant increase" in the trading volume.
Medical Developments fell 10 cents or 7.7 percent to $1.20.

MAYNE PHARMA

The Perth-based Viburnum Funds says it has increased its shareholding in Mayne Pharma from 5,236,799 shares (6.16%) to 6,360,592 shares (7.48%).
Viburnum said it bought 1,123,793 shares between June 8 and July 24, 2023 for $4,900,566 or an average of $4.36 a share.
Mayne Pharma fell seven cents or 1.5 percent to $4.61.

ANTISENSE THERAPEUTICS

Platinum Asset Management says it has become substantial shareholder in Antisense with 111,483,140 shares or 13.33 percent of the company.
The Sydney-based Platinum Asset said that on July 24, 2023 it bought 80,000,000 shares for $4,000,000 or five cents a share.
Last week, Antisense said that it had raised $8.35 million in a placement at five cents a share (BD: Jul 18, 2023).

CYNATA THERAPEUTICS

Tokyo's Fujifilm Corp says its 8,088,403 share-holding in Cynata has been diluted by a placement and that it is below five percent.
In 2017, Fujifilm said it had become a substantial shareholder in Cynata with 8,088,403 shares or 10.01 percent (BD: Feb 20, 2017).
Biotech Daily calculates Fujifilm continues to hold about 4.5 percent of the company.
Cynata was unchanged at 14.5 cents.

IDT AUSTRALIA

The Sydney-based Regal Funds says its 43,578,939 share-holding in IDT has been diluted by a placement, from 14.30 percent to 12.99 percent.
Last week, IDT said it had raised about $2.1 million through an "over-subscribed" share plan at 6.5 cents a share, taking the total raised with the recent placement to $7.1 million. (BD: Jul 20, 2023).
IDT was unchanged at seven cents.