Biotech Daily

Tuesday July 9, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CURVEBEAM UP 14%; NOVA EYE DOWN 9%**

*** QUEENSLAND UNI BLOOD TEST FOR EARLY LUNG CANCER**

*** ORTHOCELL RECORD UNAUDITED REVENUE UP 30% TO $6.7m**

*** CURVEBEAM WINS 10 PURCHASE ORDERS IN 3-MONTHS**

*** MESOBLAST RE-FILES RYONCIL FOR PAEDIATRIC GvHD TO FDA**

*** NEUROTECH ASKS FDA FOR NTI164 PANDAS/PANS ORPHAN STATUS**

*** LUMOS EXTENDS HENRY SCHEIN FEBRIDX TO BELGIUM**

*** GENETIC TECHNOLOGIES GENETYPE FOR CANADA, NEW ZEALAND**

*** ASIA UNION INCREASES, DILUTED TO 19.8% OF GENETIC SIGNATURES**

*** INSIGNIA TAKES 5% OF ARGENICA**

*** AUSBIOTECH APPOINTS DR JAMES CAMPBELL CHAIR**

MARKET REPORT

The Australian stock market was up 0.86 percent on Tuesday July 9, 2024, with the ASX200 up 66.5 points to 7,829.7 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 were down and nine traded unchanged.

Curvebeam was the best, up 2.75 cents or 13.75 percent to 22.75 cents, with 5.65 million shares traded. Proteomics was up 9.5 percent; Prescient improved 7.3 percent; Avita climbed 6.3 percent; Actinogen and Orthocell were up more than five percent; Medical Developments rose four percent; Atomo, Emvision and Syntara were up more than three percent; Genetic Signatures and Imugene improved two percent or more; CSL, Immutep, Nanosonics, Opthea and Percheron were up one percent or more; with Clarity, Cochlear, and Polynovo up by less than one percent.

Nova Eye led the falls, down 2.5 cents or 8.6 percent to 26.5 cents, with 1.55 million shares traded. Clinuvel lost six percent; 4D Medical, Compumedics and Medadvisor fell four percent or more; Micro-X and Paradigm were down more than three percent; Impedimed, Mesoblast, Neuren and Next Science shed more than two percent; Resonance was down 1.7 percent; with Pro Medicus and Resmed down by less than one percent.

THE UNIVERSITY OF QUEENSLAND

The University of Queensland says a 40-patient study shows its extracellular vesicle biomarker-based blood test can detect early-stage lung cancer.
The University of Queensland said the study found its technology “successfully differentiated patients with early-stage malignant lung nodules from those with benign lung nodules”.
The University said the nanodevice analyzed a patient’s blood sample and looked for a particular biomarker, which was the sugars that coat the messenger particles known as extracellular vesicles
The University of Queensland said the device could help patients begin treatment for lung disease before it spread.
The University said the research paper, titled ‘Glycan Profiling in Small Extracellular Vesicles with a SERS Microfluidic Biosensor Identifies Early Malignant Development in Lung Cancer’ was published in the journal Advanced Science, with the full article available at: https://onlinelibrary.wiley.com/doi/10.1002/advs.202401818.
The University of Queensland Australia Institute for Bioengineering and Nanotechnology researcher Dr Richard Lobb said lung cancer was “the most common cause of cancer death in Australia, claiming the lives of almost 9000 people each year”.
“Despite its prevalence, the initial detection and screening process for the disease can be drawn out and expensive, involving scans, imaging tests and biopsy procedures,” Dr Lobb said.
“The technology we’ve developed is non-invasive and can detect very small lung cancer nodules to hopefully catch the disease in the first stage,” Dr Lobb said.
“These sugar molecules, or glycans, serve as excellent biomarkers because the sugar code on a cancer cell is different to a normal cell,” Dr Lobb said. “A drop of blood can be all that’s needed to alert clinicians to the presence of small lung cancer nodules and allow intervention while the disease is in its early stages.”

ORTHOCELL

Orthocell says unaudited revenue for the year to June 30, 2024 was up 30.4 percent to a record $6.72 million, compared to $5.15 million in the prior corresponding period.
Orthocell said it had record revenue for the three months to June 30, 2024, up nine percent to $1.84 million compared to the previous corresponding period and up 14.4 percent compared to the three months to March 30, 2024.
The company said the increased revenue was from “impressive growth in sales” of Striate+ for dental bone regeneration and Remplir for peripheral nerve repair.
Orthocell said it currently sold Striate+ in the US, Europe, the UK, Australia and New Zealand and Remplir in Australia and New Zealand, and was “accelerating approvals to expand into new markets and geographical regions”.
The company said it had unaudited cash of $20.6 million at June 30, 2024, which would fund its operations beyond the US registration of Remplir, was expected by April 2025.
Orthocell managing-director Paul Anderson said the company had “completed a record quarter and a record year of revenue, which is an outstanding effort”.
“I am very pleased with the performance of our distribution partners and the continued increase in product adoption,” Mr Anderson said. “With a highly respected and experienced board in place, and with market-leading products, our company is in a strong position to continue to gain commercial traction and drive Remplir, our breakthrough nerve repair device, into global markets.”
Orthocell was up two cents or 5.7 percent to 37 cents.

CURVEBEAM A.I.

Curvebeam says it has 10 purchase orders for its weight-bearing imaging equipment in the three months to June 30, 2024, up from six in the previous three-months.
Curvebeam said a “purchase order” was a signed order for its weight bearing computed tomography scanner of Musculo-skeletal anatomy and its range of artificial intelligence (A.I.)-enabled, software-as-a-service-based clinical assessment products.
The company said seven of the reported purchase orders received during the quarter were for its Hirise product, four of which were in the US, with three of the orders for its other devices including its Lineup and Pedcat products.
Curvebeam said it had six orders in the three months to March 31, 2024, four in the three months to December 31, 2023 and three in the quarter to September 30, 2023, showing “a positive trend from the previous quarters with increasing market adoption” of its devices.
Curvebeam managing-director Greg Brown said the company was “very pleased to see increasing demand, and in particular for our Hirise platform, especially in the US”.
Curvebeam rose 2.75 cents or 13.75 percent to 22.75 cents with 5.65 million shares traded.

LUMOS DIAGNOSTICS

Lumos says it has extended its deal with New York’s Henry Schein to include selling its Febridx blood test to differentiate bacterial from viral respiratory infections in Belgium.
In 2023, Lumos said Henry Schein would sell its Febridx point-of-care, finger-prick blood test in Spain, Portugal and the Netherlands; and this year, said the deal included the US, Australia and New Zealand (BD: Jul 18, Aug 16, 2023; Feb 12, Jul 4, 2024).
Lumos managing-director Doug Ward said the company was “pleased to continue to partner with Henry Schein” to provide access to Febridx.
“By providing clinicians with rapid and accurate information about the nature of a patient's infection, Febridx can help health care professionals make more informed decisions about antibiotic use, ultimately benefiting both individual patients and public health,” he said.
Lumos was up 0.6 cents or 15.0 percent to 4.6 cents with 11.1 million shares traded.

MESOBLAST

Mesoblast says it has resubmitted its biologics licence application for Ryoncil for children with graft-versus-host disease to the US Food and Drug Administration.
Earlier this year, Mesoblast said that 2018 phase III study data “appears sufficient” for a biologics application for Ryoncil, or remestemcel-L, for paediatric steroid-refractory acute graft versus host disease (SR-aGVHD) (BD: Mar 26, 2024).
Today, the company said its filing addressed “remaining chemistry, manufacturing and control items” and if accepted the submission was expected to have a review period of between two and six months from receipt.
Mesoblast chief executive Prof Silviu Itescu said the company had worked closely with the FDA and thanked it for guidance “facilitating the potential approval of Ryoncil and addressing the urgent need for a therapy … [for] in children with SR-aGVHD”.
In 2020, following a 2018 phase III trial of remestemcel-L in 55 children with graft-versus-host disease, the FDA said it required a further trial of remestemcel-L and “recommended that [it] conduct at least one additional study in adults and/or children (BD: Oct 2, 2020).
Last year, Mesoblast said the FDA had provided a second complete response letter requiring more data for approval; and later, said it expected to contract the Blood and Marrow Transplant Clinical Trials Network for a phase III trial (BD: Aug 4, Nov 15, 2023).
Mesoblast fell 2.5 cents or 2.2 percent to $1.095 with 15.9 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it has applied to the US Food and Drug Administration for orphan drug designation for its marijuana-based NTI164 for paediatric neuro-psychiatric disorders.
Neurotech said the application was for NTI164 as a treatment of paediatric autoimmune neuro-psychiatric disorders associated with streptococcal infections (Pandas) and paediatric acute-onset neuro-psychiatric syndrome (Pans).
Last year, the company said a 15-patient, phase I/II trial of NTI164 for children with Pandas/Pans met its primary endpoint for anxiety and depression, with a 30 percent improvement in overall symptoms from high severity at baseline to low severity from week four onward (p = 0.016) (BD: Oct 6, 2023).
Earlier this year, Neurotech said the trial showed “further improvements” in children with neuro-psychiatric disorders at 24 weeks (BD: Feb 21, 2024).
Today, the company said orphan drug designation qualified it for incentives including tax credits for qualified trials, exemption from user fees and a potential seven years of market exclusivity post-approval, and it expected a response “within three months of filing”.
Neurotech was unchanged at 7.4 cents with 1.4 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has begun commercializing its saliva-based Genetype risk assessment tests in New Zealand and Canada.
Last month, Genetic Technologies said its Genetype multi-risk test would be distributed by Los Angeles’ Stayhealthy Inc in North America (BD: Jun 5, 2024).
Today, the company said the Genetype risk assessment test distribution would be directed by Stayhealthy’s Canada and New Zealand operations.
Genetic Technologies chief executive officer Simon Morriss said the company was “anticipating accelerated growth as we enter Canada and New Zealand.”
“Coupled with our expansion into new territories, our full-scale marketing efforts have successfully increased consumer awareness and trust that is translating into unprecedented growth,” Mr Morriss said.
Genetic Technologies fell 0.6 cents or 7.9 percent to seven cents.

GENETIC SIGNATURES

Christopher Abbott and Asia Union say they have increased and been diluted in Genetic Signatures from 37,584,516 shares (22.79%) to 44,949,035 shares (19.84%).
The Sydney-based Mr Abbott and Asia Union said they acquired shares between January 25 and July 8, 2024 through the rights issue and shortfall.
Last week, Genetic Signatures said its one-for-5.82 retail rights offer at 75 cents a share raised $8.5 million, taking the total with its placement and institutional offer to $30 million (BD: Jul 5, 2024).
Genetic Signatures was up two cents or 2.9 percent to 72 cents.

ARGENICA THERAPEUTICS

Melbourne’s Insignia Financial Ltd says it has become a substantial shareholder in Argenica with 6,274,450 shares, or 5.072 percent.
Insignia said it bought and sold shares on market between April 16 and July 4, 2024, with the largest purchase 4,038,462 shares on April 16 for $2,100,000, or 52 cents a share.
Argenica was unchanged at 93 cents.

AUSBIOTECH

Ausbiotech says it has appointed interim chair and Patrys managing-director Dr James Campbell as its permanent chair.

Ausbiotech said Dr Campbell was initially appointed as a director of Ausbiotech in April 2021 and had been interim chair since November 2023.

The industry organization said during this time Dr Campbell had “brought significant focus to Ausbiotech’s role as the leading voice to government, investors and the international community on behalf of Australia’s growing life sciences sector”.

Ausbiotech said Dr Campbell’s appointment as permanent chair followed “a unanimous request from, and vote of, the board”.