Biotech Daily

Tuesday March 26, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: MESOBLAST UP 45%; EMVISION DOWN 6%**

*** CLARITY UNDERWRITTEN $121m CAPITAL RAISE**

*** AROVELLA PLACEMENT RAISES $12.5m**

*** OSTEOPORE 'CRANIAL, LONG BONE SCAFFOLD SAFE, EFFECTIVE'**

*** ANU LINKS GENE MUTATION TO PSORIATIC ARTHRITIS, IN MICE**

*** IMRICOR: FDA OKAYS NORTHSTAR 3-D MAPPING FOR VISION-MR TRIAL**

*** ENLITIC EXTENDS UNILABS ENDEX RADIOLOGY BY $3.2m**

*** AVECHO STARTS PHASE III TPM-MARIJUANA INSOMNIA TRIAL**

*** MESOBLAST: FDA OKAYS 2018 TRIAL DATA FOR GvHD APPLICATION**

*** RACE RECEIVES 1st GMP I-V RC220 FOR PHASE I TRIAL**

*** CICADA OPENS WESTMEAD HEALTH HUB; IISHIELD 1st RESIDENT**

*** TOLL, CSL OPEN SEQIRUS TULLAMARINE WAREHOUSE**

*** ALTERITY RECEIVES $3.9m FEDERAL R&D TAX INCENTIVE**

*** GENETIC TECHNOLOGIES TAKES $600k RADIUM RDTI LOAN**

*** VIBURNUM, COLEMAN INCREASE, DILUTED TO 25% OF UNIVERSAL BIO**

*** ALEXANDER BEARD, HANCOCK & GORE TAKE 7.2% OF UNIVERSAL BIO**

*** M-D BRENT BARNES INCREASES, DILUTED TO 5.5% OF LBT**

*** MICROBA TO RELEASE 48m ASX ESCROW SHARES**

*** PHILLIP HAINS REPLACES RADIOPHARM DIRECTOR DR MICHAEL BAKER**

*** BOTANIX APPOINTS GRAEME MORISSEY CFO**

MARKET REPORT

The Australian stock market fell 0.41 percent on Tuesday March 26, 2024, with the ASX200 down 31.7 points to 7,780.2 points. Sixteen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and two were untraded. All three Big Caps fell.

Mesoblast was the best, up 15 cents or 45.45 percent to 48 cents, with 85.5 million shares traded. Cynata and Prescient climbed more than eight percent; Atomo was up 3.45 percent; Genetic Signatures, Nova Eye and Opthea rose more than two percent; Actinogen, Compumedics, Immutep, Medical Developments, Nanosonics, Percheron (Antisense) and Telix were up more than one percent; with Clinuvel and Pro Medicus up by less than one percent.

Emvision led the falls, down 16 cents or six percent to $2.52, with 45,359 shares traded. Next Science and Universal Biosensors lost five percent or more; Micro-X, Paradigm and Syntara (Pharmaxis) fell four percent or more; 4D Medical, Amplia, Orthocell and SDI shed more than two percent; Avita, Dimerix, Impedimed, Neuren, Proteomics and Resmed down one percent or more; with Cochlear, CSL, Cyclopharm and Polynovo down by less than one percent.

CLARITY PHARMACEUTICALS

Clarity says it expects to raise $121 million at $2.55 a share in a fully-underwritten $101 million placement and a fully-underwritten $20 million, one-for-33 rights offer.
Clarity said the offer price was a 12.5 percent discount to the five-day volume weighted average price of $2.915.
The company said the funds would be used to progress its radio-pharmaceutical products towards clinical trial milestones up-to 2026, including its Sar-bis-prostate specific membrane antigen (PSMA), Sar-Bombesin and Sartate.
Clarity said the pro-rata, accelerated, non-renounceable entitlement offer included an institutional offer which closed today and a retail offer, with a record date of March 28, would open on April 4 and close on April 19, 2024.
The company said Bell Potter was the sole underwriter and joint lead manager with Wilsons Corporate Finance.
Clarity was in a trading halt and last traded at $2.85.

AROVELLA THERAPEUTICS

Arovella says it has raised $12.5 million in a placement to institutional and sophisticated investors at 10.0 cents a share, or a 23.1 percent discount to the last traded price.
Arovella said investors would receive one attaching option for every share purchased, exercisable at 15 cents each in three years.
The company said the funds would be used to progress its ALA-101 for non-Hodgkin's lymphoma to a phase I trial as well as its invariant natural killer T-cell therapy for solid tumours and working capital purposes.
Arovella said it would seek shareholder approval for the issue of the options at an extraordinary general meeting, which expected to hold in May 2024.
The company said MST and Blue Ocean Equities were joint lead managers to the placement.
Arovella was unchanged at 13 cents with 9.0 million shares traded.

OSTEOPORE

Osteopore says it has recruited 11 of a hoped-for 20 patients in its trials of cranial and long bone reconstruction scaffolds, and that its device was “safe and effective”.
In 2021, Osteopore said it would sponsor two trials of 10 patients each at Brisbane’s Princess Alexandria Hospital to evaluate and validate the clinical use of its three-dimensional-printed poly-caprolactone-tricalcium phosphate cranial and long bone reconstruction scaffolds (BD: Aug 27, 2021).
Today, the company said the cranial reconstruction trial and long bone reconstruction trial had recruited nine patients and two patients, respectively.
Osteopore said both long-bone reconstruction patients had progressed well in post-surgery recovery but that “due to the stagnant recruitment process and the considerable duration of the study … the clinical trial shall cease recruitment”.
The company said the primary endpoints of the studies were formation of regenerated bone to protect the brain and bone that enabled weight-bearing.
The company said treatment outcomes had shown its cranial device was “capable of restoring vascularity within the scaffold while directing bone regeneration, when combined with the surgical technique of regenerative matching axial vascularization”.
Osteopore said it was pursuing a device designation with European regulatory authorities for market access in Europe, which did not have a five cases per year minimum, unlike the Australian Therapeutic Goods Administration.
Osteopore was unchanged at 6.5 cents.

AUSTRALIAN NATIONAL UNIVERSITY

The Canberra-based Australian National University says its staff have discovered a gene mutation responsible for causing psoriatic arthritis, in mice.
The University’s Dr Chelisa Cardinez said that if two copies of the mutated gene IKBKB were present, patients might develop psoriatic arthritis, leaving them with joint pain, stiffness and swelling.
The University said that its staff “know what causes the progression from a skin-only disease to a skin and joint disease”, a chronic inflammatory skin disease that causes patients to develop red, scaly and itchy patches across their body.
The research article, titled ‘IKK2 controls the inflammatory potential of tissue-resident regulatory T cells in a murine gain of function model’ was published in Nature, with the full article available at: https://www.nature.com/articles/s41467-024-45870-3.
The University said it was hoped that the findings would lead to improved diagnosis and treatment for patients with psoriasis and psoriatic arthritis.
“Using a mouse model, we identified that this mutation led to an abnormal function in a group of immune cells known as regulatory T-cells,” Dr Cardinez said.
“These cells are normally considered gatekeepers of the immune system [but] we found that this mutation alters the function of these cells, causing them to contribute to inflammation and promote the onset of disease,” Dr Cardinez said.
The ANU said psoriasis and psoriatic arthritis were forms of autoimmune disease, occurring when the immune system attacked healthy cells after wrongly perceiving them as a threat; three in 10 Australians with psoriasis developed psoriatic arthritis, and while there was no cure for psoriasis, there were treatments to help manage the condition.
Dr Cardinez said: “Studies have shown that delays in psoriatic arthritis diagnosis is linked to worse clinical outcomes for patients”.
“Therefore, earlier detection and treatment of these immune diseases is key to improving health outcomes,” Dr Cardinez said.

IMRICOR MEDICAL SYSTEMS

Imricor says the US Food and Drug Administration (FDA) approved the use of its Northstar mapping system in its cardiac ablation catheter trial for atrial flutter ablation.
In 2022, Imricor said that the Northstar-MR used Siemens magnetic resonance imaging (MRI) scanners and removed "the reliance on others to develop 3-D mapping systems needed for complex ablation procedure" (BD: Dec 15, 2022).
Earlier this year, the company said it had approval for an up-to 91-patient trial of its Vision-MR cardiac ablation catheter and irrigation pump products at three sites in the US, Switzerland and France (BD: Jan 21, Mar 8, 11, 2024).
Today, Imricor said the FDA approved an investigational device exemption supplement to include its Northstar-developed 3-D mapping system in its clinical trial.
The company said the original investigational device exemption approval pre-dated the completion of the Northstar mapping system and meant the system was not included.
Imricor said before use in the trial, the Northstar system would require institutional review board approval at each trial site.
Imricor executive chair Steve Wedan said the approval of Northstar was "a significant step forward toward Northstar's commercialization in the US".
"This [investigational device exemption] supplement allows the Northstar 3-D mapping system to be used by clinical sites participating in the … trial, allowing us to gather valuable user data on the system, which will help support its eventual FDA clearance via the 510(k) process," Mr Wedan said.
"In addition, sites participating in the trial will have the benefit of Northstar's capabilities for their procedures," Mr Wedan said.
Imricor was unchanged at 56.5 cents.

ENLITIC INC

Enlitic says it has a $US2.1 million ($A3.2 million) contract extension with the Geneva-based Unilabs for its Endex radiology software.
Enlitic said the extended and expanded agreement meant its Endex software would be used at additional Unilab tele-medicine clinics.
Enlitic was untraded at 65 cents.

AVECHO BIOTECHNOLOGY

Avecho says it has begun recruiting its 519-patient, phase III, clinical trial of tocopheryl phosphate mixture (TPM)-enhanced oral, soft-gel marijuana capsules for insomnia.
Earlier this month, Avecho said the Australian Therapeutic Goods Administration had approved the phase III trial, with no changes to the study design (BD: Mar 14, 2024).
Today, the company said the trial was "the largest insomnia study of its kind testing cannabidiol" and would compare nightly doses of 75mg and 150mg cannabidiol (CBD) with placebo for eight weeks at sites in Melbourne, Sydney, Perth and Queensland.
Avecho chief executive officer Dr Paul Gavin said the trial would "aim to prove, with meticulous trial design and regulatory compliance, a place for [cannabidiol] in the treatment of insomnia".
"It presents an incredible commercial opportunity for Avecho, and we look forward to first working toward interim analysis results by the end of the calendar year," Dr Gavin said.
Avecho fell 0.1 cents or 20 percent to 0.4 cents with 36.7 million shares traded.

MESOBLAST

Mesoblast says 2018 phase III study data “appears sufficient” for a biologics application for remestemcel-L for paediatric steroid-refractory acute graft versus host disease.
Mesoblast said the US Food and Drug Administration informed it that data from its MSB-GVHD001 phase III study “appears sufficient” for a biologics licence application for remestemcel-L for paediatric steroid-refractory acute graft versus host disease (GvHD).
Mesoblast chief executive Prof Silviu Itescu said that “the responses and guidance from FDA are clear and provide us with a high level of confidence to refile our [biologics licence application] for remestemcel-L in children with [steroid-refractory acute GvHD]”.
Mesoblast said it intended to file the resubmission during the next quarter, or by July 2024, seeking to address all remaining product characterization issues.
In 2018, the company said that 38 of 55 children (69%) in its open-label, phase III trial of remestemcel-L for acute graft versus host disease survived to 180 days; and 33 of the 38 children (87%), who responded to its mesenchymal stem cell treatment at day-28 were alive at day-100 with the treatments well-tolerated (BD: Sep 20, 2018).
In 2020, Mesoblast fell as much as 44.7 percent to $2.81 on news that the FDA required a further trial of remestemcel-L for graft versus host disease and “recommended that [it] conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for … graft versus host disease” (BD: Oct 2, 2020).
Last year, Mesoblast said the FDA had provided a second complete response letter requiring more data for marketing approval (BD: Aug 4, 2023).
In November, Mesoblast said it expected to contract the Blood and Marrow Transplant Clinical Trials Network for a US phase III adult trial of remestemcel L for graft-versus-host disease (BD: Nov 15, 2023).
Mesoblast climbed 15 cents or 45.45 percent to 48 cents with 85.5 million shares traded.

RACE ONCOLOGY

Race says it has received its first batch of 2,600 vials of good manufacturing practice (GMP) intra-venous (I-V) infusion bisantrene-based RC220 for an Australia phase I trial.
Last year, Race said it would pay the Ghent, Belgium-based Ardena Holding NV about $US1 million ($A1.5 million) to provide good manufacturing practice-standard RC220 intravenous bisantrene (BD: Jul 12, 2023)
Today, the company said the RC220 batch met the manufacturing quality specifications required for intra-venous products to be used in phase I and II clinical studies in Asia-Pacific, Europe and the US.
Race chief executive officer Dr Daniel Tillett said “reaching this point in the development of bisantrene is a major milestone and accomplishment”.
“The original developers of bisantrene, Lederle Laboratories, tried for nearly a decade to make a formulation of bisantrene that could be delivered via a peripheral vein without success,” Dr Tillett said.
“I, along with the entire team at Race, are looking forward to completing the [good laboratory practice] toxicology testing of RC220 in the coming months and beginning the clinical program that will give patients access to bisantrene in a format that is both easier and safer to use,” Dr Tillett said.
Race chief medical officer Dr Michelle Rashford said receiving the batch was “a major milestone to have reached and means we have manufactured RC220 to a standard suitable to start our phase I clinical trial here in Australia”.
Race was up half a cent or 0.4 percent to $1.37.

CICADA INNOVATIONS, NEW SOUTH WALES GOVERNMENT

Cicada says it has opened a ‘Healthtech Hub’ at Sydney's Westmead Health and Innovation District with support of about $8 million from Investment New South Wales.
Cicada said the Hub aimed to expedite the commercialization of medical research, focused on cell and gene therapy, cancer research and vaccines.
The company said that the Hub would provide startups, spinouts and established businesses with workspaces, connections and curated support services.
Last year, Sydney’s Cicada says it had launched an “incubator” at Westmead Health and Innovation District with the Brandon Bio-Catalyst, managed by Brandon Capital. a collaboration of more than 50 medical research institutes, investors, and government “to progress the next generation of medical therapies and technology which improve health and save lives” (BD: Aug 3, 2023).
Today, Cicada said that the first resident Iishield was developing an ‘ischemic injury protective jacket’ to improve kidney transplant procedures, aiming to double available transplant times by reducing kidney heat during procedures.

CSL, TOLL GROUP

Toll says with CSL it will construct a 10,000m^2 facility at Tullamarine, Melbourne to supply raw materials and distribute products from CSL’s Seqirus manufacturing plant.
A media release from the Toll Group, owned by Tokyo’s Japan Post Holdings, said it was a supply chain partner to CSL Seqirus, and the 10,000m^2 (2.47 acre) warehouse and distribution centre was being built to support CSL Seqirus’ operations, with construction expected to begin in August 2024.
According to its website “CSL Seqirus manufactures and in-licences … vaccines, anti-venoms and pharmaceutical products”.
Toll said the centre would be located beside CSL’s Seqirus site, which was still in construction and it would handle finished goods distribution and supplying raw materials and packaging.
The company said the facility aimed to increase “efficiency and timeliness through just-in-time services”.
Toll head of government and defense Perry Singh said the company was “proud to strengthen our partnership with CSL Seqirus and expand our footprint in the healthcare logistics sector”.
“This new facility exemplifies our commitment to delivering high-quality, tailored supply chain solutions to meet the evolving needs of our customers," Mr Singh said.
“The facilities are part of Toll’s broader multi-million-dollar investment creating advanced warehouse management solutions to meet the changing dynamics in the healthcare sector, and providing customers with the logistical support they need,” Mr. Singh said.
CSL fell $1.22 or 0.4 percent to $282.47 with 389,751 shares traded.

ALTERITY THERAPEUTICS

Alterity says it has received $3.9 million from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.
Alterity said the incentive related to research and development expenditure for the year to June 30, 2023.
The company said it would use the funds for its phase II trials of ATH434-201 and ATH434-202 in multiple system atrophy, planning a phase III trial and working capital.
Alterity was up 0.05 cents or 12.5 percent to 0.45 cents with 2.3 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has taken a Radium Capital loan of $600,000 at 1.33 percent monthly interest against its expected research and development tax incentive.
Genetic Technologies said the loan from Melbourne's Radium Capital was 80 percent of its expected Federal Government Research and Development Tax Incentive for the six months to December 31, 2023.
The company said the "short-term loan" was secured against its research and development tax incentive for the year to June 30, 2024, and would be used for working capital, but did not state the loan-term.
Genetic Technologies was up half a cent or 3.7 percent to 14 cents.

UNIVERSAL BIOSENSORS

Viburnum and director Craig Coleman says they have increased and been diluted in Universal Biosensors from 56,077,221 CDIs (26.47%) to 57,552,221 CDIs (24.87%).
The Perth-based Viburnum Finds Pty Ltd and Mr Coleman said that between June 9, 2022 and September 11, 2023 they bought 375,000 Chess depository interests (CDIs) for $124,000, or 33.1 cents each, and on March 25, 2024 they converted options to 1,000,000 CDIs for $200,000, or 20 cents each.
According to Commsec, Mr Coleman is Viburnum's executive chair.
Last week, Universal Biosensors said it had raised $2.5 million at 15.0 cents a CDI in a placement, with a $10 million one-for-3.46 rights offer to follow (BD: Mar 22, 2024).
Universal Biosensors fell one cent or five percent to 19 cents.

UNIVERSAL BIOSENSORS

Hancock & Gore Ltd says it has become substantial in Universal Biosensors with 16,666,667 shares, or 7.20 percent.
In a substantial share-holder notice signed by executive chair Alexander Beard, Sydney's Hancock & Gore said that with HGL Investments Pty Ltd and H&G High Conviction Ltd they bought the 16,666,667 shares on March 22, 2024 for $2,500,000, or 15 cents a share (see above).

LBT INNOVATIONS

LBT managing-director Brent Barnes says he has increased and been diluted in the company from 72,121,797 shares (6.73%) to 73,153,047 shares (5.48%).
Mr Barnes said that on December 19, 2023 he received 1,031,250 shares in lieu of a bonus worth $24,750, or 2.4 cents a share, and was diluted by 1.34 percent between December 20, 2023 and March 25, 2024.
In December, the company said it had placed the remaining $500,000 shortfall from its $4.5 million, four-for-one rights offer at 0.5 cents a share (BD: Dec 8, 2023).
LBT fell 0.05 cents or 1.9 percent to 2.55 cents with 1.9 million shares traded.

MICROBA LIFE SCIENCES

Microba says it will release 48,031,314 shares from ASX escrow on April 5, 2024.
According to its most recent filing, Microba had 399,820,663 shares on offer, so following the release from escrow, it would have 447,851,977 shares on offer.
Microba was up two cents or 10.3 percent to 21.5 cents.

RADIOPHARM THERANOSTICS

Radiopharm says its chief financial officer and joint company secretary Phillip Hains has replaced resigning non-executive director Dr Michael Baker.
Radiopharm said Dr Baker had been director since February 2021 and “had provided valued contributions and experienced counsel to the company”.
Radiopharm was up 0.1 cents or 1.8 percent to 5.7 cents.

BOTANIX PHARMACEUTICALS

Botanix says it has appointed Graeme Morissey as its chief financial officer.
Botanix said Mr Morissey had more than 17 years’ experience in accounting, and had worked for Grant Thornton, Klynveld Peat Marwick Goerdeler (KPMG) and Ernst & Young.
According to his Linkedin profile, Mr Morissey held a Bachelor of Commerce from Hamilton, Ontario’s McMaster University.
Botanix was up one cent or 5.3 percent to 20 cents with 3.8 million shares traded.