Biotech Daily

Wednesday November 11, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMUGENE UP 21%; ANTISENSE DOWN 9%**

*** DATA BOARD BACKS MESOBLAST REMESTEMCEL-L COVID-19 TRIAL**

*** ANTISENSE RAISES $7.3m, EMA COMMITTEE BACKS ATL1102 FOR DMD**

*** NEUROSCIENTIFIC: ALPHASWISSE PLACEMENT RAISES $2.4m**

*** AVITA Q1 REVENUE UP 55.7% TO $6.9m**

*** CORRECTION: AVITA AGM**

*** CYNATA STARTS PHASE III CYP-004 OSTEOARTHRITIS TRIAL**

*** TBG: SARS-COV-2 RAPID ANTIGEN TEST WINS CE MARK**

*** MEDLAB: UK NATIONAL INSTITUTE ACCEPTS NANABIS PHASE III TRIAL**

*** BOTANIX: FDA OKAYS CANNABIDIOL BTX1801 ANTI-MICROBIAL PLAN**

*** PRESCIENT RECEIVES $1m R&D TAX INCENTIVE**

*** REGAL FUNDS TAKES 7.5% OF HYDRIX**

*** EXOPHARM CEO DR IAN DIXON DILUTED TO 20%**

*** VISIONEERING APPOINTS THORNEY'S ANDREW SILVERBERG DIRECTOR**

MARKET REPORT

The Australian stock market was up 1.72 percent on Wednesday November 11, 2020, with the ASX200 up 109.2 points to 6,449.7 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 16 fell, and two traded unchanged.

Imugene was the best on no news, up 1.3 cents or 20.97 percent to 7.5 cents, with 63.1 million shares traded. Telix climbed 12 percent; Amplia and Neuren rose more than nine percent; LBT was up 8.3 percent; Cynata climbed 6.55 percent; Actinogen, Compumedics, Mesoblast, Paradigm, Prescient and Universal Biosensors improved more than four percent; Resonance rose 3.2 percent; Cyclopharm, Impedimed, Medical Developments and Uscom were up two percent or more; Cochlear, Kazia, Nanosonics, Orthocell, Pro Medicus and Starpharma were up one percent or more; with CSL up 0.6 percent.

Antisense led the falls, down one cent or 8.7 percent to 10.5 cents, with 11.9 million shares traded. Osprey and Patrys fell more than four percent; Alterity and Opthea were down more than three percent; Avita, Nova and Pharmaxis shed more than two percent; Dimerix, Genetic Signatures, Immutep, Next Science, Optiscan and Resmed were down more than one percent; with Clinuvel, Polynovo and Volpara down less than one percent.

MESOBLAST

Mesoblast says an interim review has approved its phase III trial of remestemcel-L for Covid-19-related acute respiratory distress syndrome (Ards) to continue unchanged.
Mesoblast said that the independent data safety monitoring board approved continuation of the 300-patient, randomized, controlled trial following the second interim analysis of 135 patients, 45 percent of the total target.
The company said that the trial's primary endpoint was all-cause mortality within 30 days of randomization and all safety data, with the key secondary endpoint "days alive off mechanical ventilatory support within 60 days of randomization".
In September the data safety monitoring board reviewed the first 30 percent of the total target and "recommended continuation of the phase III trial" (BD: Sep 4, 2020).
In April, the company said it began enrolling the trial after 10 of 12 ventilator-dependent Covid-19 Ards patients survived in a trial at New York's Mt Sinai Hospital, with nine no longer requiring ventilator support (BD: Apr 24, 30, May 6, 2020).
Today, Mesoblast said the third and final interim analysis, when 60 percent of the randomized target completed 30 days of follow-up, would occur "in the coming weeks".
Mesoblast chief medical officer Dr Fred Grossman said that patients who had co-morbidities or were older were "likely to continue to be at high risk of Ards and death, even if Covid-19 vaccines become available".
"This is why having a potential treatment that reduces mortality in these patients is so important," Dr Grossman said.
Mesoblast said that Ards was the principal cause of death in Covid-19 infection and was thought to be due to a dysregulated immune response in the lungs.
Mesoblast was up 15 cents or 4.8 percent to $3.28 with 6.9 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has raised $7.3 million through an oversubscribed placement at 10 cents a share and a European committee backs orphan status for ATL1102.
Antisense said it hoped to raise a further $1 million through a share purchase plan at the same price, which was at a 13 percent discount to the last closing price and a 2.3 percent discount to the five-day volume weighted average price to November 9, 2020.
The company said that shareholders at the record date of November 10 would be able to apply for up to $30,000 worth of shares, with the share plan opening on November 18 and closing on November 26, 2020.
Antisense said the funds would be used to manufacture drug compound and supplies for the proposed phase IIb trial of ATL1102 for Duchenne muscular dystrophy (DMD), to advance plans for ATL1102 with the US Food and Drug Administration, advance new indication initiatives and for general working capital.
Antisense said Wilsons Corporate Finance and Morgans Corporate were joint lead managers to the placement.
In a separate announcement, the company said the European Medicines Agency committee for orphan medicinal products had provided a positive opinion for ATL1102 for Duchenne muscular dystrophy.
Antisense said orphan drug designation in Europe was granted based on a positive opinion from this committee, which had been forwarded to the European Commission to decide on the recommendation.
Antisense fell one cent or 8.7 percent to 10.5 cents with 11.9 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has commitments from the Geneva's Alpha Swisse Partners to raise $2.4 million through a placement at 28 cents a share.
Neuroscientific said the issue price was at a 6.8 percent discount to the 15-day volume weighted average price.
The company said it would use the funds to finish pre-clinical safety and toxicology program in ophthalmology and neurology, accelerate the start of a phase I study in glaucoma and start a phase I study to support its neuro-degenerative indications.
Neuroscientific said Westar Capital was lead manager to the placement and would receive a six percent fee and 1,600,000 unlisted options, exercisable at 45 cents within two years.
Neuroscientific was up 1.5 cents or five percent to 31.5 cents.

AVITA THERAPEUTICS

Avita says revenue for the three months to September 30, 2020 was up 55.7 percent to $US5,060,000 ($A6,940,372) compared to the previous corresponding period.
Avita said net loss after tax for the three months was up 186.8 percent to $US10,227,000 and it had cash and cash equivalents of $US65,753,000 at September 30, 2020 compared to $US22,656,000 at September 30, 2019.
Avita chief executive officer Dr Mike Perry said the company "saw a very encouraging recovery in procedure volumes and new account openings in our fiscal first quarter, and while we still expect to see some impacts due to the [Covid-19] pandemic, we think our sales trajectory [of Recell spray-on skin for wound repair] within burns is back on track".
"Looking ahead, we are driving forth our efforts to leverage the Recell system in other markets and have been particularly encouraged by the patient and physician interest and enrolment levels we've experienced in our vitiligo trial," Dr Perry said.
Avita fell 13 cents or 2.1 percent to $5.97 with 1.1 million shares traded.

AVITA THERAPEUTICS

Yesterday's headline and article correctly reported dissent of up to 46.9 percent at Avita's annual general meeting.
Biotech Daily was unable to establish at the time of publication whether the votes were US shares or Australian Chess depository instruments (CDIs).
Today, Avita confirmed the votes were US shares each equivalent to five Australian CDIs.
The penultimate paragraph should have said that Biotech Daily believed Avita had the equivalent of 108,116,435 CDIs on issue, meaning the 4,289,735 votes opposed to compensation amounted to 21,448,675 CDI equivalents or 19.8 percent of the company (and not 3.97 percent, as stated) and sufficient to call extraordinary general meetings.
No sub-editors were hurt in making this correction.

CYNATA THERAPEUTICS

Cynata says it has begun a 440-patient, phase III, randomized, controlled trial of its Cymerus mesenchymal stem cell product CYP-004 for osteoarthritis.
In June, Cynata said it had ethics approval for the trial to assess the effect of CYP-004 on clinical outcomes and knee joint structure over two years (BD: Jun 18, 2020).
Today, the company said an initial four patients would be assessed for four weeks at two centres in Sydney and Tasmania, before begin enrolment more widely in early 2021.
Cynata was up 5.5 cents or 6.55 percent to 89.5 cents.

TBG DIAGNOSTICS

TBG says it has Conformité Européenne (CE) mark approval for its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid antigen test.
In March, TBG said it had CE mark approval for a Covid-19 ribonucleic acid (RNA)-based in-vitro diagnostic kit (BD: Mar 18, 2020).
Today, the company said 46.65 percent China subsidiary TBG Xiamen manufactured and would export the test for sale in Europe and countries that accepted CE marking.
TBG said the test was a lateral flow assay that detected the presence of the Sars-Cov-2 virus in human throat and nasal swab samples.
TBG was in an ASX suspension and last traded at 27 cents.

MEDLAB CLINICAL

Medlab says the UK National Institute for Health Research will support its Nanabis marijuana phase III cancer bone pain trial.
Medlab said it the Institute would provide support for the set-up, recruitment and delivery at two clinical sites in the UK, with site feasibility near completion.
The company said it was currently preparing an investigational new drug application with the US Food and Drug Administration in late 2020 and would initiate the pivotal phase III study in Australia, the US and the UK.
Medlab chief executive officer Dr Sean Hall said that “as use of medicinal cannabis increases under various compassionate use schemes, there is growing interest from clinicians and regulators to see clinical evidence to support claims and ensure patients can have access to validated products that have proven efficacy, safety and tolerability”.
“Medlab has one of the most clinically advanced medicinal cannabis treatments for pain and this is generating significant interest in the global investment and medical communities,” Dr Hall said.
“We have a highly purified cannabinoid that has been scientifically optimized to improve performance, with the potential to provide a much-needed alternative to opioid treatment for cancer-related pain,” Dr Hall said.
Medlab was unchanged at 18.5 cents.

BOTANIX PHARMACEUTICALS

Botanix says the US Food and Drug Administration has advised that its proposed drug development plan and data package for its synthetic cannabidiol BTX1801 is sufficient.
Botanix said that following a pre-investigational new drug meeting, it would be able to begin clinical development of BTX1801 anti-microbial to support the application.
In August, Botanix said it had begun recruiting an up-to 60 patient, phase IIa study of its nasal-route BTX1801 to prevent surgical site infections, including Staphylococcus aureus, or golden Staph, and methicillin-resistant Staphylococcus aureus (BD: Aug 12, 2020).
Today, the company said its phase IIa trial, held in Western Australia, was fully enrolled and on-track to be completed this year.
Botanix said that following completion of the study, it would begin clinical development in the US and the FDA had encouraged the company to request fast track designation.
Botanix was up one cent or 10.5 percent to 10.5 cents with 12.4 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says it has received $1,030,602 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Prescient said the rebate related to expenditure for the year to June 30, 2020.
Prescient was up 0.3 cents or 4.8 percent to 6.5 cents with 3.3 million shares traded.

HYDRIX

Regal Funds Management says it has become a substantial shareholder in Hydrix with 11,614,200 shares or 7.48 percent of the company.
The Sydney-based Regal Funds said that between July 27 and November 6, 2020 it acquired 18,828,962 shares (12.1%) for $3,787,330 or an average of 20.1 cents a share.
Regal Funds told Biotech Daily that it was not required to disclose the disposal of shares in the period stated.
Hydrix was up one cent or 3.5 percent to 29.5 cents.

EXOPHARM

Exopharm chief executive officer Dr Ian Dixon says his 27,975,294 share-holding in the company has been diluted from 23.44 percent to 20.10 percent.
The Melbourne-based Dr Dixon said that he was diluted on November 9, 2020 following the issue of 19,873,667 shares, following approvals at an extraordinary general meeting.
Exopharm was unchanged at 33.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering says it has appointed Andrew Silverberg as a director through a private placement agreement with Thorney Investment Group.
Last year, Visioneering said it had commitments to raise $3.0 million through a private placement to Thorney, who would nominate a director to its board (BD: Dec 30, 2019).
Today, the company said Mr Silverberg was an investment manager for Thorney and had more than 20 years' experience as an investor.
Visioneering said that Mr Silverberg was previously the senior portfolio manager for New York's Talpion Fund Management, a Mark Asset Management executive and was a portfolio manager for Fred Alger Management.
The company said Mr Silverberg held a Bachelor of Science from Brooklyn College.
Visioneering was up 0.1 cents or 3.2 percent to 3.2 cents with 2.1 million shares traded.