Biotech Daily

Thursday May 24, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 18%; FACTOR DOWN 11%**

*** REVA FANTOM 24-MONTH LOW MACE RATE**

*** CYNATA TREATS LAST PHASE I CYP-001 GVHD PATIENT**

*** RUSSIA APPROVES BENITEC BB-401 HEAD NECK CANCER TRIAL**

*** SOMNOMED EXPECTS 2017-'18 REVENUE UP 13%**

*** EUROPEAN PATENT FOR ORTHOCELL CELGRO**

*** US PATENT FOR USCOM SPIROSONIC LUNG FUNCTION MONITOR**

*** ADMEDUS 34% REMUNERATION REPORT 1st STRIKE**

*** USCOM LOSES SHANGHAI DIRECTOR DAVID HE**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Thursday May 24, 2018 with the ASX200 up 4.6 points to 6,037.1 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and one was untraded.

This week's worst, Optiscan, was today's best, up one cent or 17.9 percent to 6.6 cents with 293,257 shares traded, followed by Polynovo up 12.96 percent to 61 cents with 3.1 million shares traded, having completed enrolment for its European registration burn trial.

Reva climbed 7.3 percent; Oncosil improved 3.45 percent; Actinogen, Impedimed, Orthocell, Prana and Universal Biosensors rose more than two percent; Nanosonics, Neuren, Pharmaxis, Pro Medicus and Telix were up more than one percent; with CSL, Cyclopharm, Medical Developments and Resmed up by less than one percent.

Factor Therapeutics led the falls, down 0.4 cents or 9.1 percent to four cents with 1.6 million shares traded.

Bionomics lost 7.8 percent; Airxpanders was down 6.45 percent; Mesoblast fell 4.75 percent; Compumedics and Ellex were down more than three percent; Cynata shed 2.9 percent; Admedus, Avita and Starpharma were down more than one percent; with Clinuvel and Cochlear down more than one percent.

REVA MEDICAL

Reva says two-year data from its 240-patient Fantom stent trial shows a “low 5.0 percent rate of major adverse cardiac events” and a low late scaffold thrombosis event rate”.
In November last year, Reva reported two-year data from 125 patients that showed a 5.6 percent major adverse cardiac event (MACE) rate and in May, 2017 reported one-year data from 240 patients that showed a 4.2 percent MACE rate (BD: May 17; Nov 1, 2017).
Today, Reva said that two-year data, presented by Dr Alexandre Abizaid at the Paris Course on Revascularization, showed the 240-patient cohort had a 5.0 percent MACE rate and a final in-scaffold late lumen loss, that is, the difference between the vessel diameter at stenting and at follow-up, for a 36-patient subset was 0.23mm (±0.49 mm), compared 25mm (±0.40mm) at six months for a 100-patient subset.
The company previously said the study’s late lumen loss was in the desired range of 0.20mm to 0.40mm, corresponding to positive long-term outcomes.
Reva said that the two-year data showed “a single very late scaffold thrombosis event for a rate of 0.4 percent”.
The company said its next generation Fantom Encore would be available in 95-micron, 105-micron and 115-micron strut profiles for the 2.5mm, 3.0mm and 3.5mm diameters, respectively.
“The data indicate that Fantom’s advantages are translating into positive outcomes for patients,” Dr Abizaid said.
Reva was up two cents or 7.3 percent to 29.5 cents.

CYNATA THERAPEUTICS

Cynata says the eighth and final patient has been treated in cohort B of its phase I trial of CYP-001 for steroid-resistant acute graft-versus-host disease.
Cynata said that patient enrolment and dosing in the trial of its Cymerus mesenchymal stem cell product candidate had been completed, with data analysis to begin at 28 days and 100 days following treatment.
Cynata head of product development Dr Kilian Kelly told Biotech Daily that the company expected final trial results by September 2018.
The company said that evaluation of the eight patients in cohort A at day-100 showed overall survival of 87.5 percent, the overall response rate was 100 percent and the complete response rate was 50 percent (BD: Feb 27, 2018).
Dr Kelly said that treating the final patient in the phase I was “a significant milestone and great achievement for Cynata”.
“In an analysis of patients in cohort A, CYP-001 demonstrated strong efficacy and compelling patient response, as well as a lack of treatment-related serious adverse events,” Dr Kelly said. “A positive trial outcome would bring us one step closer to providing the first-ever allogenic induced pluripotent stem cell-derived mesenchymal stem cell therapy to patients in need.”
Cynata said that each dose was two million cells per kilogram of body weight, up to a maximum dose of 200 million cells, twice the cohort A dose level.
The company said that seven of the eight patients with steroid-resistant acute graft-versus-host disease were enrolled in cohort B, with one patient no longer a suitable candidate for treatment, due to a medical complication that occurred shortly after enrolment but prior to treatment with CYP-001.
Cynata said that the patient would be excluded from safety and efficacy analyses, as they did not receive CYP001 treatment.
Cynata fell 3.5 cents or 2.9 percent to $1.18.

BENITEC BIOPHARMA

Benitec says the Russian Federation has approved its 30-patient, phase II trial of BB-401 head and neck squamous cell carcinoma.

Benitec said Russia's Ministry of Health approved the trial, which followed Australian Therapeutics Goods Administration approval.

Benitec chief executive officer Greg West said the company was "able to start treating head and neck cancer patients with this promising product and we look forward to the Russian clinical centres joining the study".

The company said that the open label study was designed to explore the safety, tolerability and efficacy of BB401 following intra-tumoral injections into the lesions of patients with recurrent or metastatic head and neck squamous cell carcinoma and would enrol up to 30 patients at five to eight sites in Australia and Russia.

Benitec said that BB-401 was a recombinant DNA construct that produced an antisense RNA with specificity against epidermal growth factor receptor.

The company said that more than 90 percent of lesions from patients showed significantly increased epidermal growth factor receptor (EGFR) levels associated with head and neck squamous cell carcinoma and the goal of the study was to inhibit the expression of EGFR in the treated lesions to control the progression of disease and increase patient survival.

Benitec was unchanged at 16.5 cents.

SOMNOMED

Somnomed says it expects its core revenue for the year to June 30, 2018 to be up about 13 percent to $54 million compared to the previous corresponding period.

Somnomed said it expected the unaudited full-year revenue to increase 12 to 13 percent to an unaudited $53.5 million to $54 million.

The company said its expected unaudited revenue for the six months to June 30, 2018 would be between $28.5 million and $29 million, a 19 to 21 percent increase over the corresponding period last year.

The company said the update related to its "core business" of Somnodent sleep apnoea devices and its direct-to-consumer business Renew Sleep Solutions Inc.

Somnomed fell 26 cents or 9.7 percent to $2.43.

ORTHOCELL

Orthocell says it has been granted a European patent for its Celgro collagen medical device platform for soft tissue regeneration and repair.

Orthocell said the patent, titled 'Method for Producing a Collagen Membrane and Uses Thereof' provided additional intellectual property to protect its Celgro product platform until June 12, 2033.

The company said the patent covered the method of manufacture of new bio-scaffolds to aid in the surgical repair of soft tissue injuries.

Orthocell said patents for Celgro had been granted in the US, China, Canada, Singapore, Australia and New Zealand.

Orthocell managing director Paul Anderson said the patent was "an important addition to our current European and global [intellectual property] portfolio and further strengthens our … position".

"This comes at a perfect time for the company as we drive product adoption and sales of Celgro in Europe," Mr Anderson said

Orthocell was up one cent or 2.8 percent to 36.5 cents.

USCOM

Uscom says the US Patent and Trademark Office has granted a patent for its Spirosonic lung function monitors.

Uscom said the patent, titled 'Ultrasonic flow meter including a single transmitting transducer and a pair of receiving transducers' provided intellectual property to protect technology central to its Spirosonic monitors until December 5, 2028.

The company said the patent described technology based on "digital transit time ultrasound that improves on the current ultrasonic spirometers and provides research quality pulmonary monitoring in the home care or clinical environment".

Uscom chief executive officer Prof Robert Phillips said the company's philosophy "is to be practice leading and allowance of our US patent is further recognition of the leadership of our Uscom science".

"Uscom is currently in the process of seeking regulatory approval for Spirosonic devices in China and the US," Prof Phillips said.

"The devices are already European certified and being utilized in a number of Euro Grant research projects," Prof Phillips said.

"Importantly, the new Uscom patent can also be applied to industrial applications to improve the accuracy for any fluid flow monitoring including … oil and petroleum," Prof Phillips said.

Uscom was unchanged at 17 cents.

ADMEDUS

The Admedus annual general meeting gave the remuneration report a 'first strike' with 17,674,663 votes (34.25%) against and 33,929,028 votes (65.75%) in favor.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting, and if passed by more than 50 percent of votes, the directors must stand for re-election at a subsequent meeting within 90 days.

In announcing the resignation of Mathew Ratty earlier this week the company said it had withdrawn the resolution to re-elect Mr Ratty (BD: May 21, 2018),

Today, the Admedus meeting results said that the resolution to elect Mr Ratty would had 15,192,109 proxy votes (31.00%) against, 29,008,110 proxy votes (59.18%) in favor and 4,810,253 proxy votes (9.82%) at the proxy's discretion.

The company said there was similar dissent against the ratification of shares for Partners for Growth with 16,107,088 proxy votes (32.94%) against, 28,095,504 proxy votes (57.45%) in favor and 4,695,243 proxy votes (9.61%) at the proxy's discretion.

Admedus said the approval of 1,435,630 options exercisable at 37 cents within 10 years for chief executive officer Wayne Paterson was passed with 40,711,433 votes (82.73%) in favour, 3,798,036 votes (7.72%) against and 4,695,243 votes (9.55%) at the proxy's discretion, and the 10 percent placement facility was passed by a similar margin.

Admedus said that "notwithstanding the low number of votes cast against the remuneration report, the board takes this first strike very seriously and will work with shareholders over the coming months to understand their concerns".

The company's most recent Appendix 3B new issue announcement said Admedus had 272,462,201 shares on issue, meaning that the votes against the remuneration report amounted to 6.49 percent of the company, sufficient to requisition extraordinary general meetings.

Admedus fell half a cent or 1.7 percent to 29.5 cents with 1.2 million shares traded.

USCOM

Uscom says its Shanghai, China-based director Chao Xina David He has “resigned to pursue personal corporate opportunities”.

Uscom appointed Mr He a director in 2016 saying the former Johnson & Johnson head of Asia Pacific business development would “strengthen the connections between Uscom and the Chinese medical market” (BD: Mar 23, 2016).