



Biotech Daily

Monday September 17, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: REVA UP 17%; ITL DOWN 14%**
- * **RACE HIRES NSF FOR BISANTRENE FDA PATHWAY**
- * **GENETIC TECHNOLOGIES 'INVITED' TO MARKET CANCER TEST IN CHINA**
- * **MESOBLAST: TASLY WINS CHINA APPROVALS**
- * **MICRO-X RECEIVES \$4m FEDERAL R&D TAX INCENTIVE; LOAN REPaid**
- * **IMPEDIMED VOTES ON 2.5m CEO OPTIONS, 3m 'PERFORMANCE' RIGHTS**
- * **RESAPP REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **IMAGION TAKES CAPITAL RAISING HALT TO SUSPENSION**
- * **ACORN BELOW 5% IN TELIX**
- * **ZHANG LISHAN, STAR BRIGHT, ASSOCIATES TAKE 19.99% OF ADMEDUS**

MARKET REPORT

The Australian stock market was up 0.32 percent on Monday September 17, 2018 with the ASX200 up 19.7 points to 6,185.0 points. Thirteen Biotech Daily Top 40 stocks were up, 21 fell, three traded unchanged and three were untraded.

Reva was the best, up 3.5 cents or 17.1 percent to 24 cents with 42,761 shares traded.

Neuren climbed 5.1 percent; Airxpanders, Genetic Signatures and Telix improved more than four percent; Immutep and Osprey rose more than two percent; Mesoblast, Orthocell and Pro Medicus were up more than one percent; with Clinuvel, Ellex, Nanosonics and Resmed up by less than one percent.

ITL led the falls, down 2.5 cents or 14.3 percent to 15 cents, with 4,000 shares traded.

Prescient lost 8.2 percent; Opthea and Optiscan fell more than six percent; Actinogen shed 5.45 percent; Dimerix, Imugene and LBT fell more than four percent; Bionomics and Paradigm were down more than three percent; Avita, Benitec, Compumedics, Medical Developments and Oncosil shed two percent or more; CSL, Cynata, Factor Therapeutics and Impedimed lost one percent or more; with Cochlear, Polynovo, Starpharma and Volpara down by less than one percent.

RACE ONCOLOGY

Race says it has hired NSF Health Sciences for its US Food and Drug Administration investigational new drug application for Bisantrone for acute myeloid leukaemia.

Race said that the Washington DC-based advisory firm NSF would prepare, review, and submit its application for Bisantrone's further clinical development.

The company said that NSF would incorporate FDA meetings and comments, assemble non-clinical and clinical modules for the application from previous clinical studies and published literature, in addition to incorporating the proposed clinical trial protocol and investigator's brochure.

Race said the cost of the NSF program was \$US69,900 (\$A97,712).

The company said that NSF would act as its US agent with the FDA for correspondence, application and protocol amendments, pharmaco-vigilance and other reporting.

Race said that if the application was accepted by the FDA, it would be able to conduct a pivotal trial, which was "a key step towards US marketing approval of Bisantrone for the treatment of relapsed refractory acute myeloid leukaemia".

Race chief executive officer Peter Molloy said that NSF would help the company "navigate the process and prepare Race to start the adult registration trial in the second half of 2019".

Race said that it hoped to file the investigational new drug application by April 2019.

Mr Molloy said that once the application was accepted by the FDA, Race could submit a clinical trial protocol to conduct a rare childhood acute myeloid leukaemia study under its recently-announced rare paediatric disease designation, which could lead to "a valuable and saleable priority review voucher".

Race was unchanged at nine cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has been "invited to establish a market presence in Hainan, China".

Genetic Technologies said that Hainan Resort Software Community on behalf of Hainan Ecological Smart City Group had extended the invitation to establish its planned market entry into China through the Hainan Free Trade Zone initiative.

In August, the company said it had been "invited by representatives of the Hainan Government to discuss market entry into China" (BD: Aug 21, 2018).

Genetic Technologies said that companies approved to operate in China as part of the Hainan Free Trade Zone initiative could take advantage of significant tax benefits, subsidies and investment.

The company said that the Hainan Resort Software Community would support its market entry through the provision of Chinese company registration, free office space in the zone, marketing assistance providing a link with government sectors, hospitals and enterprise, assist in the process to obtain China Food and Drug Administration approval for its risk assessment tests, which would fast-track the process, as well as help obtain test samples to undertake new product development for the Chinese ethnic population.

Genetic Technologies executive chairman Dr Paul Kasian said the invitation was "a significant first step to advance the adoption of genetic risk assessment tests in the region".

Genetic Technologies was up 0.1 cents or 10 percent to 1.1 cents with 18.2 million shares traded.

MESOBLAST

Mesoblast says that the Tianjin-based Tasly Pharmaceutical Group has obtained all necessary approvals for its \$54 million China deal (BD: Jul 18, 2018)

In July, Mesoblast said it would receive \$54 million on closing a strategic alliance with China's Tasly Group for cardiac indications for its mesenchymal precursor cells.

The company said at that time that Tasly was "one of China's largest pharmaceutical companies" and the agreement covered the development, manufacture and commercialization in China of Mesoblast's allogeneic, or off-the-shelf, mesenchymal precursor cell (MPC) product candidates MPC-150-IM for the treatment or prevention of chronic heart failure and MPC-25-IC for the treatment or prevention of acute myocardial infarction.

Today, Mesoblast said that the approvals from the People's Republic of China included the Safe Administration of Foreign Exchange, required for closing the agreement.

Mesoblast was up two cents or 1.2 percent to \$1.70 with 744,273 shares traded.

MICRO-X PHARMACEUTICALS

Micro-X says it has received \$3,839,931 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Micro-X said the rebate related to research and development expenditure for the year to June 30, 2018.

The company said it had a \$3 million loan facility secured against the Tax Incentive, of which \$1.6 million had been drawn and had been repaid.

Micro-X was unchanged at 34 cents.

IMPEDIMED

Impedimed says investors will vote on the issue of 2,473,000 options and 2,988,000 performance rights to chief executive officer Richard Carreon.

Last year, Impedimed said that 34.88 percent of annual general meeting votes opposed the issue of 1,553,000 options to Mr Carreon but the issue of 1,262,000 performance rights was passed overwhelmingly (BD: Oct 16, Nov 15, 2017).

The company said at that time that was a 17.15 percent vote against the employee incentive plan and a 12.81 percent vote against the remuneration report, with the directors re-elected overwhelmingly.

In 2016, Impedimed avoided a remuneration report second strike and potential board spill with 84.8 percent of votes in favor, but 22.8 percent opposed an amendment to the terms of options for Mr Carreon (BD: Nov 14, 2016).

In 2015, Impedimed earned a remuneration report first strike with the annual general meeting voting 25.1 percent against the report and 25.9 percent opposing the grant of 512,500 options to Mr Carreon (BD: Oct 29, 2015).

Today, Impedimed said it proposed to issue Mr Carreon a further 2,988,000 free performance rights vesting over three years to June 30, 2021, pending clinical, regulatory and revenue targets; and 2,473,000 options, vesting in four equal annual tranches, exercisable at the 5-day volume-weighted average price to the day before grant.

The company said shareholders would vote on the remuneration report, the placement capacity and the election of directors Dr Robert Graham, Scott Ward and Gary Goetzke.

The meeting will be held at Johnson Winter and Slattery, Level 25, 20 Bond Street, Sydney on October 17, 2018 at 9am (AEDT).

Impedimed fell half a cent or one percent to 50 cents.

RESAPP

Resapp has requested a trading halt “pending the release of an announcement regarding a capital raising”.

Trading will resume on September 19, 2018 or on an earlier announcement.

Resapp last traded at 27 cents.

IMAGION BIOSYSTEMS

Imagion has requested a voluntary suspension to follow the trading halt requested on September 13, pending an “announcement ... in relation to a proposed capital raising”. (BD: Sep13, 2018).

Imagion last traded at 7.4 cents.

TELIX PHARMACEUTICALS

Acorn Capital says it has ceased its substantial shareholding in Telix due to a dilution of its holding.

The Melbourne-based Acorn said that on February 28 and June 15, 2018 it sold 1,235,714 shares for \$716,549 or 58.0 cents a share and on June 15 and 29 it bought 384,899 shares for \$255,299 or 66.3 cents a share.

Last year, Acorn said it held 10,981,250 shares in Telix or 5.56 percent, implying it retained 10,130,435 shares.

Last week, Telix issued 14,837,531 shares and 780,923 warrants as consideration for the acquisition of Atlab Pharma (BD: Sep, 11, 2018).

The company’s most recent Appendix 3B new issue announcement said it had share on 212,275,031 shares issued, implying that Acorn retained 4.77 percent of Telix.

Telix was up four cents or 4.8 percent to 87 cents.

ADMEDUS

Zhang Lishan, Star Bright Holdings and associates say they have become substantial shareholders in Admedus with 70,556,169, shares or 19.99 percent of the company.

Melbourne law firm Norton Rose Fulbright filed two substantial shareholder notices saying that the Hong Kong-based Ms Zhang controlled Star Bright, Constellation International Holdings Limited (CIHL), Constellation Immunotherapy Limited (CIL), Carron Services Ltd and Hong Kong Star Bright Management Limited, all of which had Hong Kong addresses. The notices said that with Carron Services, Ms Zhang bought 1,666,667 shares on May 16, 2018 at 30 cents a share and the entities bought \$6,888,950 in shares at 10 cents each, to be settled in three tranches on August 14, 16 and 23, 2018.

The notices included a variation allowing the third tranche of 26,289,636 shares at 13.03 cents a share to be settled on September 3, 2018, instead of August 29, 2018.

The notices said the entities acquired 25,205,974 shares on September 4, 2018 at 13.03 cents a share.

Admedus was in an extended suspension for its “recapitalization” and last traded at 13.5 cents.