Biotech Daily

Monday November 27, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BENITEC UP 26%; VIRALYTICS DOWN 9%**

*** PROTEOMICS DOMINICAN REP PROMARKERD KIDNEY TEST LAUNCH**

*** BENITEC APPLIES FOR ORPHAN STATUS FOR BB-301 FOR OPMD**

*** ORTHOCELL WELCOMES US REGENERATIVE MEDICINE FRAMEWORK**

*** OPTISCAN 45% OPPOSE OPTION, PERFORMANCE RIGHTS PLAN**

*** EEMAGINE TO ENHANCE NEUROTECH MENTE AUTISM HEADBAND**

*** ACTINOGEN REQUESTS CAPITAL RAISING HALT**

*** RHINOMED REQUESTS CAPITAL RAISING TRADING HALT**

*** G MEDICAL REQUESTS 'REGULATORY APPROVALS' TRADING HALT**

*** GENERA REQUESTS CAPITAL RAISING TRADING HALT**

*** CRESO SUSPENSION FOR CAPITAL RAISING, MARIJUANA CHOCOLATE**

*** LAI DANNY KONG SANG REDUCES TO 7% OF STEM CELL**

MARKET REPORT

The Australian stock market edged up 0.1 percent on Monday November 27, 2017, with the ASX200 up 6.2 points to 5,988.8 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and four were untraded.

Benitec was the best, up five cents or 26.3 percent to 24 cents with 764,643 shares traded. Prima climbed 4.35 percent; Acrux, Bionomics and Living Cell were up more than three percent; Admedus, Avita, Clinuvel, Cyclopharm, Ellex, Impedimed, LBT, Pharmaxis, Polynovo and Sirtex were up one percent or more; with Cochlear, CSL and Starpharma up by less than one percent.

Viralytics led the falls, down six cents or 8.6 percent to 64 cents, with 428,669 shares traded. Pro Medicus lost 6.6 percent; ITL, Nanosonics and Oncosil were down more than three percent; Neuren, Orthocell and Volpara shed more than two percent; Medical Developments and Osprey were down more than one percent; with Airxpanders, Opthea, Resmed and Reva down by less than one percent.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it will launch its Promarkerd predictive diagnostic test for diabetic kidney disease in in the Dominican Republic, on February 8, 2018.

Proteomics said the launch by the Santo Domingo, Dominican Republic-based Macrotech Farmacéutica would be “a key milestone” triggering a payment with royalties on each test.

The company said that Macrotech Farmacéutica was “the exclusive provider of dialysis services in the Dominican Republic” and was responsible for the primary production process for the in-vitro diagnostic version of the Promarkerd test.

Proteomics said the Macrotech Farmacéutica agreement had a net present value of $US1.5 million over its first nine years.

The company said that the Dominican Republic had a population of 10.6 million people, with about 505,000 adult diabetes patients, compares to one million diabetes patients in Australia, 29 million in the US and 110 million in China.

Proteomics said that early detection with Promarkerd allowed for early intervention and could delay or prevent the onset of disease, with potential savings for healthcare systems.

Proteomics said it was commercializing Promarkerd in the US for specialist laboratory testing, allowing fast adoption of a new test in advanced markets, whereas the in-vitro diagnostic would follow a traditional regulatory process, and the use of dual technology platforms enabled the roll-out tailored to respective markets.

The company said there were no drugs approved for diabetic kidney disease, but 21 drugs were in clinical trials for the condition and Promarkerd could be used as a companion diagnostic to monitor patients during trials to measure efficacy.

Proteomics said that it was in discussions with potential partners to market the test in the US, Mexico, Japan, Australia, China and Europe.

Proteomics was up one cent or 5.9 percent to 18 cents.

BENITEC BIOPHARMA

Benitec says it has applied to the US Food and Drug Administration for orphan drug designation for BB-301 for oculo-pharyngeal muscular dystrophy.

Benitec said that BB-301 was a single-vector, gene therapy construct system which used DNA-directed RNA interference (ddRNAi) to silence expression of the mutant gene associated with oculo-pharyngeal muscular dystrophy (OPMD), while adding back a copy of the normal version of the same gene to restore gene function.

The company said that FDA orphan drug designation required the indication affected fewer than 200,000 people in the US, and there be sufficient information to establish a medically plausible basis for expecting the product to be an effective treatment.

Benitec said that orphan drug designation included a seven-year market exclusivity on product approval, tax credits, assistance in regulatory proceedings and full exemption from the FDA's drug registration fees.

Benitec chief executive officer Greg West said the submission followed European Medicines Agency orphan drug designation and BB-301 had “the potential to be a valuable asset in the treatment of OPMD”.

Benitec said it had completed pre-investigational new drug application and scientific advice meetings with the FDA, Health Canada and several European agencies to discuss the regulatory development pathway for BB-301 as a treatment for OPMD and to ensure the proposed development program addressed regulatory expectations.

The company said that it intended to file an investigational new drug application and start a human clinical study by the end of 2018.

Benitec climbed five cents or 26.3 percent to 24 cents.

ORTHOCELL

Orthocell says it welcomes a new US Food and Drug Administration “comprehensive regenerative medicine policy framework”.
Orthocell said the framework “greatly advantages [its] market entry plans”.
The FDA said on November 16, 2017 that the framework “aims to spur innovation, efficient access to potentially transformative products, while ensuring safety and efficacy”.
The FDA framework and supporting documents are available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm585345.htm.
The FDA said that the framework for the development and oversight of regenerative medicine products, including novel cellular therapies was outlined in four guidance documents and built on the FDA’s existing risk-based regulatory approach to more clearly describe what products were regulated as drugs, devices, and/or biological products.
The US regulator said the documents proposed an efficient, science-based process to ensure the safety and effectiveness of the therapies, while supporting development.
The FDA said the documents defined a risk-based framework for the FDA to focus its enforcement actions against those products that raise potential significant safety concerns, and “delivers on important provisions of the 21st Century Cures Act”, signed into law on December 13, 2016 to accelerate medical product development.
Orthocell managing director Paul Anderson said the FDA announcement provided “a more defined pathway for Orthocell’s US market entry plans, which is strategically focused on commercializing its regenerative medicine product portfolio”.
Orthocell fell one cent or 2.6 percent to 38 cents.

OPTISCAN IMAGING

Optiscan says shareholders cast 46,245,584 votes (45.2%) against the option and performance rights resolution with 55,976,054 votes (54.8%) in favor.
Optiscan said that the resolution was passed along with all other annual general meeting resolutions with all other resolutions passed easily.
The company’s most recent Appendix 3B new issue announcement said that Optiscan had 425,978,800 shares on issue, meaning that the votes against the option and performance rights resolution amounted to 10.9 percent of the company, sufficient to requisition extraordinary general meetings.
Optiscan was unchanged at 9.5 cents.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says it has an agreement with Berlin’s Eemagine Medical Imaging Solutions GmbH to enhance its Mente autism headband.
Neurotech said that Eemagine was a member of the Neuromotion Group, a holding company for businesses which develop, sell and service equipment and services for the study and treatment of human brain function in clinical and research applications.
Neurotech was up 2.5 cents or 14.7 percent to 19.5 cents.

ACTINOGEN

Actinogen has requested a trading halt “pending an announcement regarding a capital raising”.
Trading will resume on November 29, 2017 or on an earlier announcement.
Actinogen last traded at 4.8 cents.

RHINOMED

Rhinomed has requested a trading halt “pending an announcement in relation to a proposed capital raising”.
Trading will resume on November 29, 2017 or on an earlier announcement.
Rhinomed last traded at 15 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical has requested a trading halt “pending an announcement regarding regulatory approvals within Australia and New Zealand”.
Trading will resume on November 29, 2017 or on an earlier announcement.
G Medical last traded at 42.5 cents.

GENERA BIOSYSTEMS

Genera has requested a trading halt “pending an announcement … regarding [an] … agreement … in relation to its Ampasand molecular diagnostic testing menu”.
Genera said the “co-marketing partnering agreement” … was with “a major [in-vitro-diagnostics] company”.
Trading will resume on November 29, 2017 or on an earlier announcement.
Genera last traded at 20.5 cents.

CRESO PHARMA

Creso says it has requested a voluntary suspension pending an announcement in relation to a capital raising, company update and its marijuana terpene chocolate.
Creso last traded at $1.345.

STEM CELL UNITED

Lai Danny Kong Sang says he has reduced his substantial holding in Stem Cell United from 32,419,378 shares (8.89%) to 28,419,378 shares (6.83%).
The Singapore-based Mr Sang said he sold 4,000,000 shares for $240,000 or six cents a share on November 23, 2017.
Stem Cell fell half a cent or 8.5 percent to 5.4 cents with 5.2 million shares traded.