Biotech Daily

Thursday August 8, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ALLIED HEALTH UP 9%, VIRALYTICS DOWN 6%**

*** BENITEC, NSW UNI BETA III TUBULIN GENE FOR LUNG CANCER LICENCE**

*** REGENEUS $12m FAT STEM CELLS FOR MUSCULOSKELETAL IPO**

*** IMUGENE UP 60% ON LINGUET VITAMIN D 'MELTLET', PARTNER TALKS**

*** BLUECHIIP STEM CELL, BLOOD BAG CRYO-PRESERVATION CASSETTE**

*** ADVANCED SURGICAL ORTHOFIX DISTRIBUTION DEAL, SPINAL SALE**

*** ONCOSIL HIRES EMERGO FOR REGULATORY PATHWAYS**

*** BIONICHE $8m PLACEMENT AT 30.7 CENTS**

MARKET REPORT

The Australian stock market rebounded 1.07 percent on Thursday August 8, 2013 with the S&P ASX 200 up 53.5 points to 5,064.8 points.

Fifteen of the Biotech Daily Top 40 stocks were up, four fell, 10 traded unchanged and 11 were untraded.

Allied Health was the best, up half a cent or 9.3 percent to 5.9 cents with 5.6 million shares traded.

Antisense and Patrys climbed more than eight percent; Benitec was up 5.2 percent; Alchemia, Nanosonics, QRX and Sirtex were up four percent or more; Acrux and Starpharma were up more than three percent; Anteo, Bionomics, CSL, Resmed and Universal Biosensors rose more than one percent; with GI Dynamics and Mesoblast up by less than one percent.

Viralytics led the few falls, down two cents or 6.25 percent to 30 cents with 49,300 shares traded; followed by Phylogica falling five percent; Atcor and Prana shed more than three percent; with Cochlear down 1.3 percent.

BENITEC BIOPHARMA

Benitec says it has licenced the beta III tubulin gene as a target from the University of New South Wales for its Tribetarna lung cancer program.

Benitec chief executive officer Dr Peter French told Biotech Daily that licence granted Benitec exclusive rights to use its RNA-interference technology to silence the University of New South Wales-developed target, the beta III tubulin gene, to overcome chemotherapy resistance in non-small cell lung cancer.

Dr French said the licence allowed for both the development and commercialization of a companion diagnostic to aid in the identification of patients with non-small cell lung cancer at risk of developing resistance to chemotherapy as well as an RNA-interference treatment.

Dr French said that the terms of the acquisition of the licence were confidential but could be assumed to be non-material.

Benitec said that Tribetarna had been in a research collaboration with the University of New South Wales' Children's Cancer Institute Australia.

The company said that the data to date had demonstrated the efficacy of the approach in a preclinical model of human lung cancer.

Benitec said that the licence enabled it and its partners to advance to toxicity testing in preparation for a clinical trial as well as developing a diagnostic, which was "integral to future clinical and commercialization plans".

The company said that advanced stage lung cancer was associated with a very poor prognosis due to rapid development of resistance to chemotherapy drugs by the tumor cells and as a result, current treatment regimens generally had a modest and limited effect on the course of the disease, with the resistance shown to be associated with the beta III tubulin gene.

Benitec said that genetic therapy using DNA-directed RNA-interference (ddRNAi) to knock down the beta III tubulin gene was a new approach to improving the effectiveness of chemotherapy drugs, significantly prolonging survival and representing a high potential opportunity for its gene silencing technology.

Benitec chief business officer Carl Stubbings said that "using a companion diagnostic to identify patients at risk of developing resistance to chemotherapy, adds a new dimension to Tribetarna's potential ability to meet a critical medical need".

"It is an important part of the development program and will enhance the overall value of this treatment," Mr Stubbings said.

"Therapies that include a companion diagnostic will assist in tailoring the right therapy to the right patient," Mr Stubbings said.

"Furthermore companion diagnostics increase the chances of clinical trials meeting their endpoints," Mr Stubbings said.

Dr French said that having demonstrated strong proof of principle and executed the licence agreement with the University of New South Wales, "we are in a position to move to the next step of the program which is to undertake toxicity testing in preparation for a clinical trial".

"Benitec's recent successful $10.7 million capital raising has provided the company with an opportunity to move Tribetana into the clinic in the latter part of 2014," Dr French said.

The University of New South Wales technology transfer company Newsouth Innovations chief executive officer Dr Kevin Cullen said the University was "delighted to be entering into this licencing agreement with Benitec Biopharma Ltd after a significant and successful research collaboration over the last few years."

Benitec was up 1.5 cents or 5.2 percent to 30.5 cents.

REGENEUS

Regeneus hopes to raise up to $12 million and list on the ASX to commercialize its adipose-based stem cells for musculoskeletal and other inflammatory conditions.
Regeneus said it hoped to raise $10 million with the availability to raise a further $2 million at 25 cents a share.
The company said that a $12 million raising would value the company at $47,477,218 and was being jointly managed and led by Peloton Capital and BBY stock brokers.
Regeneus said that the offer was expected to open on August 13 and close on August 30, 2013 with an expected listing on the ASX under the code RGS on September 11, 2013.
Regeneus executive chairman John Martin said the funds raised would allow the business to develop, trial and commercialize its adipose-derived from fat tissue cell therapies that can be used to treat musculoskeletal and other inflammatory conditions in humans and animals.
“Our IPO will be the first Australian biotechnology float since 2011,” Mr Martin said.
“We have been encouraged by the local and global interest in the offer as well as from our existing shareholder base and hope that it contributes to the growing investor demand in the biotechnology sector,” Mr Martin.
Details are available at http://regeneus.com.au/investor-centre/ipo.

IMUGENE

Imugene says it has completed formulation for its Linguet form of vitamin D and is in commercialization discussions with Australian vitamin manufacturers and suppliers.
Imugene said the Linguet vitamin D tablet melted in the mouth, was known as ‘meltlet’ and was designed to address the unpleasant taste of vitamins and alleviate stress for people who had difficulty in swallowing some forms of vitamin tablets.
The company said that the Linguet supported buccal administration of drugs through the lining of the mouth, but a fast melt vitamin was a new application of the technology.
Imugene executive director Dr Nick Ede said that 50 percent of the general population reported difficulty swallowing large capsules and tablets.
“We are utilising our knowledge base around Linguet to create a rapid melt-in-the-mouth formulation that will fill a need in the global vitamin market predicted to be worth $30 billion by 2015,” Dr Ede said.
Imugene was up 0.3 cents or 60 percent to 0.8 cents with 43.4 million shares traded.

BLUECHIIP

Bluechiip says has released a locakable cassette for the storage of platelet and plasma concentrates such as cord blood, incorporating its Cryotag tracking technology.
Bluechiip said that the lockable cassette was designed to hold blood bags was “a significant improvement in the storage and handling of plasma concentrates for the bio-bank industry”.
The company said that it had applied for a patent for the cassettes, which were stored in a rack or a frame inside a liquid nitrogen tank and the Cryotag enabled real-time tracking of the identity and temperature history of the stored products throughout their lives.
Bluechiip said the cassette overcame problems with existing cassettes and further safeguarded stored blood components against temperature variability, were 76 percent cooler when removed from liquid nitrogen, easier to handle, had a clear window, could be color-coded for sample identification and had an anti-slip mechanism.
Bluechiip was unchanged at 17.5 cents.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical says it has a 12 month transitional services agreement with the Lewisville, Texas- based Orthofix Inc's subsidiary, Orthofix Australia Pty Ltd.
Advanced Surgical said it would provide distribution services as Orthofix Australia developed a direct sales force.
The company said that "as a result of the new arrangements, [Advanced Surgical's] existing spinal business … has been acquired by Orthofix Australia".
Advanced Surgical said the transaction continued its focus of strengthening the balance sheet and allows it to focus on its orthopaedic product range in delivering sales and profitability.
Advanced Surgical was untraded at 6.4 cents.

ONCOSIL MEDICAL

Oncosil says it has hired regulatory consultancy Emergo Group to review the data for its Oncosil device to establish a regulatory path for the US Food and Drug Administration.
Oncosil said that the "gap analysis" by the Austin, Texas-based Emergo was an important step in defining the regulatory pathway to a pre-investigation device exemption meeting with the FDA.
The company said it was developing its Oncosil an implantable device, acquired from Psivida as Brachysil, which emits radiation directly into the pancreatic tumor and the pain-conducting nerves surrounding it.
Oncosil said its device delivered radiation therapy locally for up to three months and was inserted directly into the centre of the tumor in a 15 to 30 minute procedure.
Oncosil said that Emergo had "extensive experience in supporting medical device submissions globally, and particularly in the US".
The company said that an investigational device exemption involved the submission of manufacturing data, a protocol, an investigators brochure and any clinical safety and efficacy data generated to date, to permit a pivotal clinical study in the US.
Oncosil said that with Emergo it would determine whether a simple reference device comparison approach known as a 510(k) submission or a pre-marketing authorization was appropriate.
The company said that it hoped to begin a pivotal clinical study in 2014 to provide data on the safety and efficacy of the device.
Oncosil chief executive officer Dr Neil Frazer said the Emergo Group was also providing support for the regulatory process and commercialization of Oncosil in Europe.
Oncosil was unchanged at nine cents with 1.4 million shares traded.

BIONICHE LIFE SCIENCES

Bioniche says it will offer shares at 29 Canadian cents (30.7 Australian cents) each in its placement to raise up to $C7.5 million ($A8.06 million) (BD: Aug 7, 2013).
Bioniche said that one warrant would be issued with every two new shares acquired, exercisable at 40 Canadian cents (42.3 Australian cents) within two years of issue.
Bioniche was untraded at 34.5 cents.