

# Biotech Daily

Monday July 30, 2012

Daily news on ASX-listed biotechnology companies

- \* ASX UP, BIOTECH DOWN:
  - ALLIED HEALTH, USCOM UP 20%, PHYLOGICA DOWN 11%
- \* BENITEC, MEDISTEM ARTICLE BACKS ddRNAi FOR TRANSPLANT
- \* CALZADA, POLYNOVO BROADEN NOVOSORB TRIAL FOR RECRUITMENT
- \* REGENEUS, CRYOSITE COLLABORATE ON FROZEN FAT STEM CELLS
- \* CBIO EGM TO BECOME INVION FOR ANTI-INFLAMMATORY DISEASES
- \* ISONEA EGM VOTES PASS EASILY 15% OPPOSE PURSUIT OF HAPPINESS
- \* NANOSONICS APPOINTS COCHLEAR'S MICHAEL KAVANAGH DIRECTOR

### MARKET REPORT

The Australian stock market climbed 0.85 percent on Monday July 30, 2012 with the S&P ASX 200 up 35.9 points to 4,245.7 points.

Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, 11 traded unchanged and one was untraded. All three Big Caps were up.

Allied Health and Uscom were equal best, both up 20 percent to 1.8 cents and 12 cents, respectively, with 587,000 shares and 25,000 shares traded, respectively, followed by Bioniche up 15.2 percent to 53 cents, Compumedics up 14.3 cents to 7.2 cents and Psivida up 13.5 percent to \$2.61.

Benitec climbed 5.9 percent; Prima was up 4.2 percent; Resmed was up three percent; Clinuvel and Ellex rose more than two percent; with Biota, Cochlear, CSL, Pharmaxis and Starpharma up more than one percent.

Phylogica led the falls, down 0.4 cents or 10.5 percent to 3.4 cents with 1.5 million shares traded.

Cellmid and Sunshine Heart lost more than six percent; Genetic Technologies and Impedimed fell four percent or more; Living Cell and Prana were down more than three percent; Acrux and Anteo shed more than two percent; with Alchemia, Circadian, Nanosonics, Tissue Therapies and Viralytics down one percent or more.

#### **BENITEC BIOPHARMA**

Benitec says a journal article co-authored by chief executive officer Dr Peter French validates DNA-directed RNA interference (ddRNAi) for transplant rejection. Benitec said the paper, entitled 'Induction of Alloimmune Tolerance in Heart Transplantation Through Gene Silencing of TLR Adaptors' by Dr French and the chief executive officer of the San Diego, California-based Medistem Inc Dr Thomas Ichim demonstrated the potential of ddRNAi to significantly overcome transplant rejection was published in the American Journal of Transplantation. An abstract is available at: http://onlinelibrary.wiley.com/doi/10.1111/j.1600-6143.2012.04196.x/abstract.

"This is the first time that the innate immune system has been targeted for the purpose of transplantation tolerance," Dr Ichim said.

"This is a completely different approach to what others are doing," Dr Ichim said. Benitec said the study added to the independent validation of the potential of its ddRNAi technology to provide solutions to diverse conditions.

The company said that in the study's mouse transplantation model, transplant recipients were treated with ddRNAi-expressing vectors before a fully major histocompatibility complex-mismatched heart transplantation was conducted.

Benitec said that transplanted hearts only survived five to eight days in untreated recipients, but ddRNAi alone, or in combination with a low dose of the immunosuppressant drug rapamycin, significantly prolonged the transplanted heart survival by 36.7 days and 88.8 days, respectively.

The company said the results "... provide proof-of-principle evidence that knocking down [specific genes using ddRNAi] may have the potential to prevent graft rejection in heart transplantation".

"Our association with Medistem has been fruitful in demonstrating the breadth of application of ddRNAi beyond the specific programs being pursued by Benitec directly," Dr French said. "Thanks to Medistem, prevention of heart transplant rejection along with Medistem's previously announced results in using ddRNAi in cell therapy for rheumatoid arthritis, can now be added to the ever-expanding list of applications." Benitec was up 0.1 cents or 5.9 percent to 1.8 cents.

### CALZADA, POLYNOVO BIOMATERIALS

Calzada says subsidiary Polynovo has recruited nine of 20 patients in its first human clinical trial of Novosorb polymer wound treatment (BD: Mar 19, 2012).

Calzada said that five patients in the pressure sores vacuum-assisted closure clinical trial had completed the eight week treatment, one had withdrawn "due to causes unrelated to the trial" and three were receiving treatment.

The company said that the trial data had not been formally evaluated, but "positive feedback has been received from the trial investigators".

Calzada said that no patient in the Novosorb treatment group had any adverse experience and had not had the Novosorb material replaced by the control Granufoam.

The company said that indications for such a change would include a local or systemic adverse event, directly or indirectly attributable to Novosorb

Calzada said that enrollment had been slower than planned, but a cohort of patients with heel pressure sores suitable for topical negative pressure therapy had been included.

The company said the potential patient pool had increased significantly and since the dressings were smaller and less time-consuming, it would allow a greater number of patients to be treated concurrently.

Calzada was unchanged at 4.6 cents.

### REGENEUS, CRYOSITE

Regeneus says that it will collaborate with Cryosite to jointly develop a protocol for the cryo-preservation or freezing of human regenerative stem cells.

Regeneus said that the regenerative cells could be stored as a patient's own bio-bank for future treatments of musculoskeletal conditions such as osteoarthritis.

Regeneus's head of human health Dr Richard Lilischkis said the partnership would allow it to extend the benefits of its Hiqcell procedure by storing a patient's own cells to be used as part of a future course of treatment.

The company said that Hiqcell was an in-clinic autologous cell therapy for the treatment of osteoarthritis and tendon and ligament injuries (BD: Nov, 29, 2011; Apr 5, 2012).

Regeneus said it worked with sports and orthopedic medical specialists to conduct the Hiqcell procedure of harvesting a patient's own adipose or fat tissue, extracting the regenerative cells from the tissue, processing them in-clinic and injecting the preparation in osteoarthritic-affected joints such as knees, hips and ankles of that patient.

The company said that extracted cells included mesenchymal stem cells and adipocytes, which worked together to reduce inflammation and promote regeneration and repair. Regeneus said that under the new protocol, excess cells from the tissue extraction procedure would be prepared for freezing and cryogenically stored by Cryosite under liquid nitrogen as low as minus 196oC.

The company said the stored cells could be held for an indefinite period of time until required for a future injection by the medical specialist for treatment of the patient's existing condition, in both existing and additional joints.

Regeneus said it had developed assays to ensure the viability of the cells after freezing and before future re-injection.

The company said that the added benefits of the protocol to the Hiqcell procedure included further improved medical outcomes, greater convenience and cost effectiveness and it would open the opportunity for the company to work with medical specialists who wanted to explore Hiqcell to treat other inflammatory or immune-mediated conditions such as rheumatoid arthritis, that might be well suited to a more regular course of injections. Regeneus said that Sydney Sportsmed Specialists' Dr Diana Robinson would provide medical supervisory expertise in the development of the new protocol.

Cryosite was up one cent or 4.65 percent to 22.5 cents.

Regeneus is a public unlisted company

#### **CBIO**

CBio will ask shareholders to vote on eight resolutions to ratify the merger with Inverseon to develop clinical stage treatments for anti-inflammatory diseases (BD: Jul 2, 2012). Earlier this month CBio said it proposed to merge with the San Francisco California-based Inverseon Inc to become Invion for 143,486,978 CBio shares, worth \$8,609,219 at that day's closing price of six cents a share.

Today's notice of meeting proposed the issue of 76,607,225 shares to Inverseon, the approval of financial benefits, namely the 76,607,225 shares, to Inverseon's chairman Dr William Garner and director Dr Mitchell Glass, along with 66,879,753 shares to non-Inverseon associates.

The meeting will vote to elect as directors Dr Garner, Dr Glass, Brett Heading and Dr James Campbell and change CBio's name to Invion.

The meeting will be held at McCullough Robertson, Level 11, Central Plaza Two, 66 Eagle Street, Brisbane on August 30, 2102 at 3pm (AEST).

CBio fell 0.1 cents or 1.7 percent to 5.8 cents.

# ISONEA (FORMERLY KARMELSONIX)

Isonea shareholders passed all nine extraordinary general meeting resolutions but 15.4 percent of voters opposed the issue of shares to Pursuit of Happiness Pty Ltd. Isonea director Dr Ross Macdonald told Biotech Daily that Pursuit of Happiness was a web design vendor that developed the customer interface for the Asthma Sense application and took shares in lieu of cash.

The resolution to issue 4,401,020 shares with a deemed value of 0.4 cents a share to Pursuit of Happiness attracted the strongest dissent at the meeting with 39,760,517 proxy votes (15.4%) opposed and 219,076,224 proxy votes (84.6%) in favor.

Prior to the meeting, Isonea had 2,334,657,043 shares on issue, meaning the dissent came from 1.7 percent of the total shareholding.

The resolution for a 20-to-one consolidation of the shares on issue faced 23.8 million proxy votes against, but was supported by 235,209,113 proxy votes.

Resolutions electing Dr Macdonald, Dr Stewart Washer and David Dantzker as directors and the ratification of other share issues were passed by wider margins.

Isonea fell 0.1 cents or 33.3 percent to 0.2 cents with 7.4 million shares traded.

# **NANOSONICS**

Nanosonics says it has appointed Cochlear executive Michael Kavanagh as a non-executive director.

Nanosonics said Mr Kavanagh was "a highly experienced executive" having worked for more than 20 years in healthcare marketing and was currently Cochlear's senior vice-president of marketing, a position he has held for more than nine years.

The company said that Mr Kavanagh previously worked for Pharmacia and Parke Davis. Nanosonics chairman Maurie Stang said Mr Kavanagh's "experience and depth of knowledge in global medical device market place is an invaluable addition to our board". Mr Kavanagh holds a Bachelor of Science from University College, Dublin, Ireland and Masters of Business Administration from the University of Queensland Nanosonics fell half a cent or one percent to 49.5 cents.