Biotech Daily

Wednesday January 28, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: GENETIC TECH UP 17%**
- ANTEO, UNIVERSAL BIO DOWN 8%

*** AVITA BEGINS PIVOTAL 30-PATIENT US RECELL BURNS TRIAL**

*** PROGEN: 'MEDIGEN BRINGS FORWARD PI-88 LIVER CANCER RESULTS'**

*** US PATENT FOR CIRCADIAN'S VEGFR-3**

*** NEUREN NNZ-2566 TO BE RENAMED 'TROFINETIDE'**

*** RHINOMED NEXT GENERATION TURBINE READY FOR SHIPPING**

*** GENETIC TECHNOLOGIES: VALE DIRECTOR DAVID CARTER**

*** PHYTOTECH APPOINTS DR BENAD GOLDWASSER DIRECTOR**

*** ACUVAX EX-CEO DR WILLIAM ARDREY FRAUD TRIAL BEGINS**

MARKET REPORT

The Australian stock market edged up 0.1 percent on Wednesday January 28, 2015 with the S&P ASX 200 up 5.6 points to 5,552.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 11 fell, 12 traded unchanged and five were untraded.

Genetic Technologies was the best, up 0.2 cents or 16.7 percent to 1.4 cents with 6.5 million shares traded, followed by Avita up 10.3 percent to 8.6 cents with 394,767 shares traded.

Ellex, Medical Developments and Patrys climbed more than six percent; Optiscan was up 4.9 percent; Bionomics, Nanosonics and Pharmaxis rose two percent or more; Clinuvel and Phosphagenics were up more than one percent; with CSL and Mesoblast up by less than one percent.

Anteo and Universal Biosensors led the falls, both down eight percent to 9.2 cents and 23 cents, respectively, with 8.8 million shares and 163,500 shares traded, respectively.

Neuren fell 5.9 percent; Tissue Therapies lost 4.8 percent; Acrux, Analytica and Resmed were down more than three percent; Oncosil shed 2.7 percent; Cochlear and Viralytics were down more than one percent; with Alchemia, Benitec and Impedimed down by less than one percent.

AVITA MEDICAL

Avita says the first patient has been enrolled in its 30-patient, US Food and Drug Administration-approved, pivotal phase III trial of Recell for burn injuries.

Avita said that the study was designed to confirm the safety and effectiveness of Recell in patients requiring skin grafts due to burn injuries.

The company said that the use of Recell in combination with mesh grafting reflected a clinical development strategy intended to support mainstream adoption of Recell for all burn surgeries.

Avita said that 30 subjects would be recruited so that complete follow-up data from 25 subjects can be evaluated after accounting for some attrition.

The company said that each subject would be their own control, with a portion of their injury randomly allocated to receive skin grafting (control) and a similar portion of their injury randomly allocated to receive Recell treatment in combination with meshed skin grafting that is further expanded than the control.

Avita said that the two primary effectiveness endpoints would compare donor site to treatment area expansion ratios; and incidence of complete closure assessed eight weeks after treatment by personnel blinded to the treatment received.

The company said it hypothesized that Recell would show a comparable or non-inferior incidence of complete closure but with a superior expansion of donor skin, meaning that a larger burn injury could be treated with a smaller donor site.

Avita said that donor site pain associated with burn surgery was a chief concern of burn patients.

The company said that secondary endpoints would be evaluated after 24 weeks and were hypothesized to demonstrate subject preference for the outcome of Recell treatment compared to the control, as well as superiority of the subjects' and blinded assessor rating of scar outcomes.

Avita research and technology head Andrew Quick said that the announcement marked "a significant achievement for the company as this program represents a definitive pathway to US market approval and also provides important substantiation for the positioning of the use of Recell in a clinically and economically meaningful way all over the world".

Avita said that a successful trial would yield data demonstrating the use of Recell for achieving primary wound closure with a reduced requirement for donor skin harvesting along with improved functional and aesthetic outcomes.

The company said that the use of less donor skin would result in achieving primary closure in fewer surgical procedures and a decreased length of hospital stay and reduced pain management.

Avita said that the advantage of improved functional and aesthetic outcomes was largely self-evident, but also provided a positive economic impact in terms of reduced requirements for reconstructive or scar surgery and an earlier return for patients to a normal, productive life.

The company said that in addition to supporting a pre-market approval application for the FDA to market Recell for burns in the US, the study data would be important for supporting commercialization efforts, particularly in the UK, with the National Institute for Health and Care Excellence looking for a high standard of supplemental research for their medical technology assessment of Recell.

Last year, the UK Institute said that Recell "demonstrates potential to improve healing of acute burns, [but] more evidence is required before a formal recommendation can be granted" for the treatment of skin loss, scarring and depigmentation after a burn injury and recommended it be used for larger area burns injuries (BD: Nov 13, 2014).

Avita was up 0.8 cents or 10.3 percent to 8.6 cents.

PROGEN PHARMACEUTICALS

Progen says that Taiwan licencee Medigen Biotechnology Corp will “bring forward” the analysis of its 520-patients phase III trial of PI-88 for liver cancer.

Last year, Progen reported that Medigen would continue with the trial despite an interim analysis of 131 patients showing that PI-88 failed to meet its primary endpoint of disease-free survival (BD: Jul 28, 30, 2014).

Today, the company said that at January 26, 2015, all 520 patients in the randomized, placebo-controlled trial in Taiwan, South Korea, China and Hong Kong had completed treatment.

Progen said that the trial was intended to confirm the safety and efficacy of PI-88 in the adjuvant treatment of hepatocellular carcinoma after surgical resection and patients were to be treated for 12 months with either PI-88 or placebo and receive follow-up for two years.

The company said that following the Medigen decision, other than patients receiving antiviral therapy, the patients would not receive any further follow-up beyond a final study visit to be conducted within the next 28 days.

Progen said that Medigen would execute a study conclusion plan with the clinical trial sites and investigators and after the collection of the clinical data, a comprehensive statistical analysis would be carried out and a final clinical study report prepared and submitted to the Taiwan Food and Drug Administration.

The company said that Medigen would make a decision on the next phase of PI-88 based on the final result of data analysis and discussion with regulatory authorities.

Progen said it was “seeking clarification from Medigen to understand the expected timeframe for the final results and/or the clinical study report”.

Progen was up half a cent or 2.3 percent to 22.5 cents.

CIRCADIAN TECHNOLOGIES

Circadian says has been granted a US patent protecting compositions containing soluble vascular endothelial growth factor receptor 3 (VEGFR-3) fusion proteins.

Circadian said that the patent was granted to that wholly-owned subsidiary Vegenics and the expected award of a substantial patent term adjustment extended the expiry date to June 22, 2026.

The company said that OPT-302 was a VEGFR-3 protein that blocked vascular endothelial growth factors C and D and inhibited the hallmarks of wet age-related macular degeneration in preclinical models, including blood vessel growth and vessel leakage.

Circadian said it was developing OPT-302 for the treatment of wet age-related macular degeneration through its wholly-owned subsidiary Opthea Pty Ltd.

The company said that wet age-related macular degeneration was the leading cause of blindness for people over the age of 50 in the US and Europe and was estimated to affect more than 1.5 million people worldwide, with an estimated market of $US5 billion in the US alone.

Circadian said that the equivalent patent case had been granted in Europe, Japan, Canada and Australia.

The company said that it had a further patent family directed to the OPT-302 molecule which had the potential to extend the patent protection to 2034.

Circadian was unchanged at 15.5 cents.

NEUREN PHARMACEUTICALS

Neuren says that World Health Organization has included “trofinetide” as the proposed non-proprietary name for glycyl-2-methyl-L-prolyl-L-glutamic acid, or NNZ-2566.
Neuren said that the WHO’s proposed international non-proprietary names for pharmaceutical substances was subject to a four-month period for comment before trofinetide could be confirmed as the international non-proprietary name.
The company said it was developing NNZ-2566 as a therapy for a range of neurological conditions and injuries.
Neuren said that last year it announced top-line results from its phase II clinical trial in Rett syndrome, which demonstrated clinical benefit from treatment with NNZ-2566, with three other phase II trials in progress for Fragile X syndrome, moderate to severe traumatic brain injury and concussion.
Neuren fell one cent or 5.9 percent to 16 cents with 3.8 million shares traded.

RHINOMED

Rhinomed says its “next generation” Turbine technology is substantially different in both design and materials and will start shipping on February 9, 2015.
Rhinomed chief executive officer Michael Johnson said the company had “incorporated user feedback and listened to sports physicians, coaches, users and our distributors to ensure that we respond to their needs”.
The company said that the new Turbine had been engineered “to follow the anatomy of the nose and gently and comfortably dilate the nose while firmly staying in place”.
“We knew the Turbine was helping people to control their breathing, improve airflow and allows both pro and amateur athletes alike to perform better,” Mr Johnson said.
“Some of the specific feedback gathered showed athletes wanted a product that would stay in place during severe percussive activity and one that could respond to increased nasal secretions.” Mr Johnson said.
Rhinomed said that the internal ratchet system gave the product “perfect dilation for each nostril and also enables the user to easily clear their nose without removing the device”.
The company said it had received “strong pre-orders” from its distributors.
Rhinomed was up 0.1 cents or five percent to 2.1 cents with 1.2 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says that recently appointed director David Carter has died.
Mr Carter was appointed a non-executive director in last year (BD: Sep 24, 2014).
Genetic Technologies said at that time that Mr Carter was a company director, corporate lawyer and adviser and was then a director of Thorn Group and the Group’s immediate past chair, and was formerly a director of Diabetes Australia Victoria.
The company said that Mr Carter held a Bachelor and Masters of Law from Monash University and a Bachelor of Civil Law from Oxford University.
Today, the company said that the staff and board were “deeply saddened by the early passing of Mr David Carter”.
“David will always be remembered fondly and we feel privileged to have had the pleasure of working with such a learned and warm person,” Genetic Technologies said.
“In the short time with the company his contribution was invaluable,” the company said.
“Our most heartfelt sympathy is with his family at this difficult time,” the company said.
Genetic Technologies was up 0.2 cents or 16.7 percent to 1.4 cents with 6.5 million shares traded.

PHYTOTECH MEDICAL

Phytotech says it has appointed Israeli doctor and entrepreneur Dr Benad Goldwasser as a non-executive director.

Phytotech said that Dr Goldwasser began his career in urology in 1978, working at the Chaim Sheba Medical Center in Tel Hashomer and later worked at Duke University Medical Center, Durham, North Carolina and at the Mayo Clinic in Rochester, Minnesota.

The company said that Dr Goldwasser was appointed the chairman of urology at the Chaim Sheba Medical Center and professor of surgery at Tel Aviv University and has authored or co-authored more than 120 original articles published in peer-reviewed journals and 19 book chapters in books on urology.

Phytotech said that from 1993 to 1996 Dr Goldwasser founded or co-founded Vidamed, which was acquired by Medtronic, Medinol which partnered with Boston Scientific for coronary stents, Rita Medical and Optonol which was acquired by Alcon.

The company said that in 1997, Dr Goldwasser became managing director of an Israeli venture capital company Biomedical Investments and in 2003 co-founded GI View and was its chief executive officer until April 2008 and from 2014 was chairman of cardiology company Leadexx.

Phytotech said that Dr Goldwasser would be paid director's fees and a daily consultancy rate and subject to shareholder approval he would be issued 1,500,000 unquoted options exercisable at 20 cents each vesting over three years.

The company said that Dr Goldwasser holds a medical degree and an Masters of Business Administration from Tel-Aviv University.

Phytotech fell 11.5 cents or 18.25 percent to 51.5 cents with 9.1 million shares traded.

ACUVAX

The trial of former Acuvax chief executive officer Dr William Ardrey on 19 counts of fraud, began before Justice Laurence Levy at the Perth District Court on January 27, 2015.

An officer of the Perth District Court told Biotech Daily that the trial had been set to run for 28 days.

Procedural hearings have delayed the trial which was originally set for November 18, 2013 (BD: Feb 28, Apr 20, Jul 20, Nov 30, 2012; Feb 25, Aug 7, Dec 5, 2013).

In 2012, Western Australia Police told Biotech Daily that Dr Ardrey had been granted bail with undisclosed conditions.

Western Australia Police said the complainant in the matter was Phoenix Eagle a company described as a small biotechnology company involved in therapeutic cosmetics.

Dr Ardrey resigned from Acuvax in 2011 (BD: Feb 9, 2011)

Acuvax was untraded at 0.1 cents.